

1 UNITED STATES DISTRICT COURT  
2 FOR THE DISTRICT OF NEW JERSEY

3  
4 UNITED STATES OF AMERICA, et CIVIL ACTION NUMBER:  
5 al, 3:12-cv-07758-ZNQ-JBD  
6 Plaintiffs,  
7 v. JURY TRIAL - VOLUME 7

8  
9 JOHNSON & JOHNSON, JANSSEN  
10 PRODUCTS, L.P.  
11 Defendants.

12  
13 Clarkson S. Fisher Building & U.S. Courthouse  
14 402 East State Street  
15 Trenton, New Jersey 08608  
16 May 20, 2024  
17 Commencing at 9:00 a.m.

18  
19 B E F O R E: THE HONORABLE ZAHID N. QURAISHI,  
20 UNITED STATES DISTRICT JUDGE

21 A P P E A R A N C E S:

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1 (PROCEEDINGS held in open court before The Honorable  
2 ZAHID N. QURAIISHI, United States District Judge, on May 20,  
3 2024, at 9:00 a.m.)

4 THE DEPUTY COURT CLERK: All rise.

5 THE COURT: All right, folks. You may be seated.  
6 Thank you.

7 Good morning, everybody. Let's have appearances for  
8 the day, beginning with Relators.

9 MR. MARKETOS: Good morning, Your Honor. Pete  
10 Marketos for the Relators.

11 MR. RUSS: Good morning. Josh Russ for Relators.

12 MR. WIRMANI: Good morning. Andrew Wirmani for  
13 Relators.

14 MS. WENDEL: Good morning. Whitney Wendel for  
15 Relators.

16 THE COURT: Good morning, everyone.

17 MS. BROWN: Good morning, Your Honor. Alli Brown for  
18 Janssen.

19 MR. WYATT: Good morning, Your Honor. Geoff Wyatt  
20 for Janssen.

21 MR. KLEIN: Good morning. Brad Klein for Janssen.

22 THE COURT: Good morning, folks.

23 So we have a few issues I think that we need to address  
24 this morning, but before I get to the written submissions that  
25 I've just reviewed, we have an issue with Juror Number 2 that

1 I want to alert counsel to.

2 So, Ms. Klinger, Juror Number 2, advised the Court  
3 earlier this morning that her brother unexpectedly passed away  
4 yesterday. I, through my chambers, instructed her to turn  
5 around.

6 She didn't know what to do. She was on her way to  
7 court because she didn't understand if she would be excused  
8 from jury duty. I will tell you what my intentions are is to  
9 briefly place her on the record by phone this morning just to  
10 confirm that information, since I'm getting it from my staff,  
11 just have her confirm that I intend to excuse her.

12 But I want to make sure there's no objections to that  
13 from either side. I don't know what the objection would be,  
14 but this is exactly the scenario that we contemplate when we  
15 have additional jurors is that something as tragic as this can  
16 occur during the trial, and I didn't ask her any more details  
17 about what was the cause of death.

18 I didn't ask her what the services were going to be  
19 because I think it's anticipated that -- two things: One is  
20 she was, I think, audibly distraught when she called chambers.  
21 That was what I understood. So I don't believe she would be  
22 in a position to even process what's going to happen today in  
23 trial or even the next few days.

24 And also I think we can reasonably anticipate there  
25 would be services for her brother within the time frame of the

1 trial remaining.

2 So for both those reasons, I don't see us having the  
3 ability to keep her on the jury, but let me hear from  
4 Relators' counsel first before I place that call.

5 MR. MARKETOS: No objection and wish her the best,  
6 Your Honor.

7 THE COURT: All right. Ms. Brown?

8 MS. BROWN: No objection, of course, Your Honor.

9 THE COURT: So can we do this, then? I want to place  
10 that call now just so she's not having this kind of hanging  
11 over her head.

12 Kim, do you mind doing that? And I'll briefly speak to  
13 her, extend our condolences, and excuse her.

14 (Brief pause.)

15 JUROR NO. 2: Hello?

16 THE COURT: Ms. Klinger, I don't know if you can hear  
17 me. This is Judge Quraishi calling from the courtroom.

18 JUROR NO. 2: Yes, I can hear you.

19 THE COURT: Ms. Klinger, I know you called my  
20 chambers earlier, and I just needed to confirm on the  
21 record -- and I apologize for having to do this -- but I do  
22 want to confirm on the record that I believe it's my  
23 understanding that your brother unexpectedly passed away  
24 yesterday.

25 Is that correct?

1 JUROR NO. 2: That's correct.

2 THE COURT: All right. Well, Ms. Klinger, I don't  
3 want to hold you on this call any longer than necessary. I  
4 just wanted to extend our deepest condolences from counsel and  
5 from the Court for your loss, and also that you are excused  
6 from the remaining jury duty for this trial. Okay?

7 JUROR NO. 2: Thank you so much.

8 THE COURT: All right. I wish you and your family  
9 the best.

10 JUROR NO. 2: Thank you.

11 THE COURT: All right. Thank you, Ms. Klinger.

12 THE JUROR NO. 2: Bye-bye.

13 THE COURT: Bye-bye.

14 All right, folks. Now, what's the remaining issue?  
15 This proposed instruction, Mr. Marketos?

16 MR. MARKETOS: Yeah, we just have -- we just have  
17 a -- and Mr. Russ is going to argue it, Your Honor. We can  
18 also do it after the witness is done testifying, but it's  
19 probably best to address it now.

20 It's not something that we need read before she --

21 THE COURT: No, I understand, but we have time now so  
22 why don't we address it because I don't even know if this is  
23 something I'm going to give.

24 So I have questions for both sides.

25 And, Mr. Marketos, let me ask you this first: You

1 know, one of the -- one of the challenges you raised when  
2 Janssen had a late objection was that it was untimely. Right?

3 I understand that you're not moving to strike, but your  
4 jury instruction could arguably be tantamount to striking the  
5 testimony because you're attempting to neutralize it.

6 Why isn't this proposal of this instruction untimely  
7 now that it's coming a few days later?

8 MR. MARKETOS: Well, they're permitted to ask these  
9 questions on bias and credibility. That's permitted.

10 And so if they want to ask about how she got her  
11 evidence -- they were insinuating that she was creating some  
12 of it -- that's -- they're entitled to do that.

13 So we can't get up and object if they're going into  
14 this subject matter. It's their choice. If they want to do a  
15 collateral attack on the witness, that's -- and frankly,  
16 Your Honor, we expected that.

17 All the attacks on the witnesses have not been, you  
18 know, what they're saying had happened but, instead, how  
19 they're biased or their credibility for other collateral  
20 reasons. And so they're entitled to do that.

21 We're not suggesting that Ms. Brown's not entitled to  
22 examine the witness about documents she collected, things she  
23 forwarded to her attorneys.

24 It's the implication that that's against the law when  
25 they started bringing up the ethics complaints, and so, you



1 know, the issue with the document and the metadata, and  
2 they're entitled to ask those questions. We're not saying  
3 they're not.

4 All we're asking for is an instruction so that the  
5 jurors understand that the law protects whistleblowers from  
6 investigating and passing information about that investigation  
7 on to lawyers and to --

8 THE COURT: Does that include Ms. Brancaccio's  
9 efforts to kind of disguise her efforts with MedForce, a third  
10 party, to represent that, Hey, I'm requesting these documents  
11 as a Janssen employee in furtherance of my work as a Janssen  
12 employee when she was really doing something very different  
13 there?

14 That's a very different scenario than simply forwarding  
15 Janssen documents while you're employed there, right, and the  
16 protections under the FDA and the whistleblower statute.

17 So isn't that -- at least that piece of the  
18 cross-examination different than what you're talking about?

19 MR. MARKETOS: So, Your Honor, again, cross-examine  
20 all you want is what we're saying on that front. If you want  
21 to -- if you want to talk about credibility or bias, no  
22 problem.

23 The point of that matter is, no, it's not different  
24 under the law. That MedForce depository of Janssen's  
25 prescription information about doctors they were paying --

1 THE COURT: So you're saying that the whistleblower  
2 statute protects employee at Janssen --

3 MR. MARKETOS: Yes.

4 THE COURT: -- from misrepresenting -- making  
5 material misrepresentations to a third party in order to get  
6 documents from a third party in order to support their  
7 whistleblower lawsuit.

8 MR. MARKETOS: So, Your Honor, that implication about  
9 the misrepresentation is a loaded question that was built in  
10 from counsel.

11 THE COURT: Well, I know, but for now, I'm taking  
12 their position.

13 MR. MARKETOS: Sure.

14 THE COURT: Look, I need to understand fully where  
15 you're coming from on this. I think it's one thing to say the  
16 documents are coming from Janssen. The law protects that.  
17 Janssen's saying it's a little bit twofold. That's one piece  
18 of it, right?

19 There's a second piece where at least it's alleged --  
20 at least some evidence has come out through cross-examination  
21 that the witness misrepresented the purpose of collecting  
22 those documents, not from Janssen, but from a third party,  
23 nonemployer.

24 MR. MARKETOS: Yes.

25 THE COURT: And are you telling me just separate and

1 apart -- I just want you to answer this: Is that protected  
2 under the law, and, if so, did you provide me anything to say  
3 that?

4 MR. MARKETOS: It is, Your Honor. It is protected  
5 because you're talking about -- when they're saying it's  
6 MedForce, that's the vendor that held Janssen's information.  
7 It's the employee who would otherwise be entitled to obtain  
8 that information.

9 They're saying she obtained it for the wrong purpose.  
10 They are saying the purpose in obtaining it was not because  
11 you wanted facially valid reasons to get prescription  
12 information or sales information for doctors, but that when  
13 you got that information, you were going to hand it to your --

14 THE COURT: Wait. And your point is what -- how is  
15 that any different than her sending Janssen documents from  
16 Janssen for the wrong purpose of not -- not for purposes of  
17 employment but to support her whistleblower claim?

18 MR. MARKETOS: Correct, Your Honor. That's it.  
19 They're trying to nuance it. In other words, imagine this,  
20 Your Honor: Over here you've got Janssen -- Janssen  
21 compliance. Over here you've got Janssen repository of  
22 financial information. Over here you've got MedForce, that  
23 supplies the prescription data.

24 THE COURT: Right. Let me ask you this: Why does  
25 the proposed instruction -- even if I agree you have to be

1 given that, why wouldn't this just be something that's added  
2 to the final instructions?

3 MR. MARKETOS: Well --

4 THE COURT: And, by the way, let me give you a  
5 scenario. I mean, Ms. Brown, I know either you or Mr. Wyatt,  
6 somebody is going to be chiming in for the defense, so I  
7 promise you I'll give you that opportunity.

8 But I want you to all hear me. This -- to me, this  
9 almost falls into like a scenario, and I've seen this before,  
10 maybe more in the criminal context, but it comes up in civil,  
11 right?

12 A witness is cross-examined because they have met with  
13 the attorney prior to testifying, right? There's no objection  
14 to that level of cross-examination. You see it all the time,  
15 maybe more in Government cases involving criminals where it  
16 says, You met with the Government, right? Witness A, you've  
17 never met with me, and you've met with him four times; is that  
18 right? And you met with the Government in preparation of your  
19 testimony today.

20 It is not uncommon in the final instructions of trials  
21 like that where that evidence is elicited, and I've given this  
22 instruction, and it's been upheld where there's nothing  
23 inappropriate about meeting with a lawyer. I'm paraphrasing  
24 now.

25 There's nothing inappropriate or against the law to

1 meet with a lawyer prior to testimony. In fact, that's the  
2 due diligence of a lawyer, to meet with a particular witness,  
3 so that type of instruction is given, and there's no objection  
4 to the testimony. The testimony is permissible.

5 The area of cross-examination is permissible, but  
6 instruction is given at the end of trial, one of which says,  
7 There's nothing wrong with meeting with the lawyer prior to  
8 testifying. In fact, that's normally the due diligence of a  
9 lawyer to do that. It can be malpractice if they didn't.

10 So -- and, by the way, this might be more for Janssen,  
11 but for now, because I have you, Mr. Marketos, that  
12 instruction is not given immediately after the  
13 cross-examination.

14 MR. MARKETOS: Fair enough.

15 THE COURT: It's something that's included in the  
16 final instruction that alerts the jury, Hey, you might have  
17 heard some testimony about witnesses meeting with their  
18 lawyers or with a particular lawyer prior to testifying. That  
19 in and of itself is not improper. In fact, that's the due  
20 diligence of the lawyer.

21 So I will tell you, I hear your argument. Even if I  
22 agree with you, is there anything there that would require it  
23 today versus the end of trial? Because, that, I'm not in  
24 agreement about.

25 MR. MARKETOS: No is the answer to the question,

1 Your Honor. End of trial is fine. It's because it has to do  
2 with the law we needed it from the Court.

3 THE COURT: Now, where in the papers that you  
4 submitted does the law support this context, an instruction on  
5 this issue, right?

6 In fact, it's probably not uncommon, Mr. Marketos, that  
7 a witness is cross-examined and Relators cross-examine on  
8 this, correct? Most Relators are going to be cross-examined  
9 on what they might have taken from the company and provided to  
10 the Government in furtherance of their whistleblower lawsuit.  
11 Now they're a qui tam case?

12 MR. MARKETOS: It's usually not, Your Honor. What  
13 usually happens is the defendant is -- gets upset that the --  
14 the employee blew the whistle on them and took the information  
15 and they file a counterclaim.

16 So that matter is addressed before the case even gets  
17 to trial.

18 THE COURT: That's a very different scenario. That's  
19 a very different posture. You know, Janssen is suing the  
20 employee for illegally taking documents; very different than  
21 cross-examining the bias and credibility of a witness in how  
22 they conducted themselves at the company in taking it.

23 So what I'm asking you is: Do you have a single case  
24 in the United States in which a Court has instructed on this?  
25 And if so, did you provide it, or are you going to provide it?

1 MR. MARKETOS: No, Your Honor. We haven't because  
2 there isn't a case that we found where a defendant at trial  
3 went into the issues specific to an employee taking case --  
4 evidence --

5 THE COURT: But I find that hard to believe,  
6 Mr. Marketos, and, by the way, I say this out of ignorance,  
7 right? I'm not the expert in False Claims Act; you all are,  
8 right?

9 So I'm learning a little bit as the trial goes, but  
10 you're telling me that no case in the country are Relators on  
11 the stand and nobody's cross-examining about kind of the  
12 conduct of this Relator and how did they get the documents and  
13 where they were sending them.

14 I mean, that's -- that's never been cross-examined?  
15 This is the first time in history that I'm getting an issue of  
16 first impression, because I find that doubtful?

17 MR. MARKETOS: Let me explain, if I could,  
18 Your Honor.

19 THE COURT: Sure.

20 MR. MARKETOS: There are cases where they go into --  
21 including the one case that they cite, there are cases that  
22 address that you may go into a whistleblower's collateral,  
23 taking documents that were not related to the case to show  
24 that they were a bad actor, that they were taking information  
25 that was helpful for a competitive activity or otherwise.

1           There are not cases that we have found -- and it's  
2           because of this body of law, in our view. It's because the  
3           body of law that's been developed. If you are attacking the  
4           credibility of a witness because they took the documents that  
5           are specific to the allegations in the case, it would  
6           literally undermine the purpose of the FDA in encouraging  
7           whistleblowers to do this.

8           And so all we've said is simply this: We are not  
9           saying they can't go into it, nor are we suggesting they can't  
10          cross-examine and suggest that she's a bad person, whatever  
11          Janssen wants to do. You're a bad person because you took  
12          documents that support your claims.

13          THE COURT: I don't understand that. If they're able  
14          to say she's a bad person or she's done something wrong by the  
15          cross-examination, then how do you get this instruction?

16          MR. MARKETOS: It's only about the fact that it's not  
17          against the law. It's not unlawful or inappropriate in the  
18          eyes of the law. That is the most important part. Because  
19          the law protects them.

20          Using a confidentiality agreement or a policy that  
21          Janssen has that says, Don't take our documents is trumped by  
22          the False Claims Act, and Congress has --

23          THE COURT: Well, you don't say "unlawful" in your  
24          instruction. You say "otherwise inappropriate."

25          So, you know, it may be different if your proposed



1 instruction was simply to say, although I still want to hear  
2 from Janssen, that this is not illegal conduct, that this is  
3 not illegal. But you're saying "not inappropriate," which is  
4 very broad because the whole purpose of the cross-examination  
5 is to say, Hey, something stinks here about how she did this.

6 And I think they're allowed to go through the  
7 cross-examination. I don't believe -- you can correct me if  
8 I'm wrong -- if there's anything in the transcript where  
9 Ms. Brown cross-examined Ms. Brancaccio and said, You know  
10 this is illegal, right? You know you violated the law?

11 And, by the way, I may have missed that. So,  
12 Mr. Marketos, did that come out?

13 MR. MARKETOS: Yes. She pointed to the company  
14 policy and suggested she violated -- breached the contract --

15 THE COURT: Well, a violation of company policy is  
16 different than violating the law.

17 MR. MARKETOS: But it's an agreement. This is the  
18 problem. That's -- the jurors need to understand that. All  
19 right?

20 So you knew that this was against company policy. You  
21 knew that this was against -- the insinuation is that there is  
22 a confidentiality that she's breached. Okay?

23 And, of course, what the law says -- and if you look on  
24 page 3 of our brief -- "The taking and publication of these  
25 documents were not wrongful, even in light of nondisclosure

1 agreements, given the strong public policy in favor of  
2 protecting whistleblowers who report fraud against the  
3 Government." And then the case goes on to say, "The strong  
4 public policy would be forwarded if Masimo" -- here Janssen --  
5 "could silence whistleblowers and compel them to be complicit  
6 in" --

7 THE COURT: Mr. Marketos, I read it, but here's now my  
8 follow-up to that, right? Don't I have to do an analysis that  
9 says what exactly did she take from Janssen and how is  
10 everything she took related to these claims?

11 Isn't that part of the analysis, that this strong  
12 policy is about whistleblower employees being able to collect  
13 documents and other information that are related to their  
14 case?

15 I have no idea the amount of volume of information that  
16 the Relators took in this particular case. So how can I say  
17 that all the information they took is related in some way to  
18 this whistleblower lawsuit and that they didn't cross the line  
19 and go somewhere further than that?

20 MR. MARKETOS: Your Honor, because the actual  
21 allegations in the cross-examination were specific to the fact  
22 that she was taking information to help her case.

23 This is not one -- and that was -- that was the entire  
24 subject was that the case was a setup because she was taking  
25 information that supported her case. There are no allegations

1 in this case, nor have there ever been in the years since it's  
2 been on file.

3 This has been on -- it's been unsealed since 2016,  
4 seven years. They have never alleged or insinuated that  
5 Ms. Brancaccio took information that would somehow not be  
6 related to her allegations in the case.

7 THE COURT: All right. Mr. Marketos, I hear you.  
8 For now, this is my only ruling, and I'm going to hear from  
9 Ms. Brown. The only ruling I'm giving right now is I'm not  
10 giving this instruction today.

11 MR. MARKETOS: Understood.

12 THE COURT: I am not prohibiting the instruction.  
13 I'm not making a ruling on that. I want to hear from Janssen  
14 right now. Then I'll decide. I think, for now, I'm going to  
15 table it.

16 But after I hear from Janssen, I may need more  
17 information from both counsel and, because we have some time,  
18 I think that's where I'm going to be.

19 Ms. Brown -- or Mr. Wyatt, are you going to be arguing  
20 this?

21 MR. WYATT: Yes, Your Honor.

22 THE COURT: So here's where I am. I'm not giving  
23 instruction today, so take a breath, but tell me why I  
24 shouldn't give the instruction at all.

25 MR. WYATT: Yes, Your Honor. The instruction, as the

1 Court pointed out, would instruct the jury that, in essence,  
2 they shouldn't consider this at all, not only that it's not  
3 unlawful, but also that it's not inappropriate, and that's  
4 just not true. We did cite a case.

5 THE COURT: Let's stay there. By the way, I did read  
6 the papers, folks, and I can read them again and again and  
7 again, but let me ask the particular question. I agree with  
8 you on the inappropriate part. I think that's a little fuzzy,  
9 and it's fairly vague, and it's very broad.

10 I think that would be tantamount to neutralizing the  
11 cross-examination all together.

12 But what about my other analogy, the analogy where you  
13 have a witness who's cross-examined about meeting with  
14 opposing counsel. You didn't meet with Janssen, did you? You  
15 only met with the Relators' counsel. How many times did you  
16 meet with the Relators' counsel?

17 And you got to go through that cross because you want  
18 to put before the jury that, you know, they only met with one  
19 side, and so if they're answering questions a lot smoother  
20 with one counsel, not the other, this is kind of why you're  
21 getting this.

22 And you're also putting some bias in there, right, that  
23 you didn't want to meet with opposing counsel because you have  
24 some bias towards, you know, the Relators' side of the case.

25 In a scenario like that it's not improper to give an

1 instruction -- not to say that the cross-examination should be  
2 neutralized, but that there's nothing actually, you know,  
3 inappropriate -- I'll use the word "inappropriate" in this  
4 context only, not in the one Relators did -- with meeting with  
5 counsel to go over your testimony.

6 Why can't there be some fashion jury instruction at the  
7 end of trial that talks about the conduct of the Relators at  
8 least collecting documents, not being illegal, but not  
9 necessarily getting to the appropriateness?

10 Now, stay with me there, and let me hear from you on  
11 that.

12 MR. WYATT: With respect to that, Your Honor, we  
13 haven't said that it is illegal. So that's part of it. The  
14 issue hasn't been raised.

15 I understand they're saying it's suggested, but it  
16 really hasn't been. We pointed to company policy, and the  
17 inference really is this is how far this person is willing to  
18 go, not that you can't consider the evidence, right, not that,  
19 therefore, we pursue a counterclaim against her, which is what  
20 -- the case that the Relators are all talking about.

21 But rather, it just shows, you know, intent, motive,  
22 bias, credibility, those kinds of things that I fear any kind  
23 of instruction along these lines would suggest to the jury  
24 they can't consider, and that's just wrong.

25 I mean, obviously, with a central witness like this in

1 the case, credibility and bias are very important. The case  
2 is recognized that, including in the False Claims Act context  
3 when a Relator testifies, this type of thing, including taking  
4 a document specifically, like the *Kiro* case says -- K-I-R-O --  
5 goes to that issue of credibility and bias.

6 THE COURT: Have you come across -- by the way, it  
7 wouldn't matter if it's adverse to your position, and you know  
8 that well enough. Have you come across a case in which an  
9 instruction like this has been given?

10 MR. WYATT: Looked for it, obviously, Your Honor,  
11 didn't see it, didn't see it -- and in fairness, either way.  
12 Didn't see it --

13 THE COURT: Yeah, I know. Either way. Let me ask  
14 you this: Didn't it come out in the cross-examination that --  
15 and, by the way, this is only one piece, the secret taping,  
16 didn't actually come out on cross-examination that the witness  
17 did check the law and found out it was a one-consent party  
18 state because it was New York? All those things which  
19 actually demonstrated, I think even on cross, that even the  
20 secret taping was absolutely legal, even though it was, ugh,  
21 right? It was a little yucky. No? Am I mistaken about that?

22 Mr. Marketos, I'll give you a shot. Do you remember  
23 that testimony?

24 MR. MARKETOS: Well, I remember it, Your Honor.

25 THE COURT: So, I mean, didn't that even establish

1 through Janssen that they weren't even attempting to say that  
2 what the Relator was doing was illegal? In fact, they were  
3 upholding that it was legal. It just didn't smell great or it  
4 didn't smell right and that they wanted to get into the bias  
5 about, you know, how she's there secretly taping employees,  
6 you know, folks that she works with and things of that nature.

7 But it wasn't illegal.

8 MR. MARKETOS: Yes, Your Honor. And if you are able  
9 to do that, if you are able to put those insinuations out  
10 there, these cases specifically say -- including the ones that  
11 we cited -- that's why you have a separate section starting on  
12 page 3.

13 You have to think about what they're doing. It's not  
14 merely that she's biased. How does it go to bias? I mean,  
15 they're attacking her credibility by saying, you're  
16 essentially a snitch, and the whole point of the whistleblower  
17 law that is put forth by Congress in the False Claims Act is  
18 that whistleblowers collect evidence against their employer.

19 THE COURT: While continuing to commit the same  
20 conduct?

21 MR. MARKETOS: The same conduct. She would be having  
22 to -- she would be having to move forward. They can do that  
23 all they want. They can --

24 THE COURT: No, no. Hear my question, right?

25 MR. MARKETOS: Yes.

1 THE COURT: Your scenario is -- and, by the way, I'm  
2 not saying these are the facts, but there is evidence of this,  
3 right?

4 MR. MARKETOS: Sure.

5 THE COURT: That the Relator, while checking these  
6 documents, doing all the things that you're saying are  
7 appropriate, was also admittedly continuing to commit what she  
8 believed to be illegal conduct in perpetuating the allegations  
9 in the lawsuit.

10 Isn't that part of the case --

11 MR. MARKETOS: I understand --

12 THE COURT: -- at least from Janssen's  
13 cross-examination?

14 MR. MARKETOS: Sure. And that's why -- that's why  
15 we're not complaining about it. Cross that all you want. And  
16 then we haven't said a word about it.

17 But the gathering of the evidence that they -- they're  
18 showing emails with her lawyers. This is what lawyers do,  
19 whistleblower lawyers do, in their talk -- if they want to  
20 cross-examine and say, You stayed there for all these years  
21 and you continued do it even though you felt it was wrong, no  
22 problem.

23 But when they're talking about the law and they're  
24 talking about violations of company policy, they are  
25 undermining the FDA. Every single whistleblower who gathered



1 evidence from his or her employer would be subject to this  
2 type of cross-examination, that you've done something icky and  
3 wrong when the policy encourages it. It is literally  
4 encouraged because then you have to take the evidence. You  
5 have to go to the Government, and if you don't have it, your  
6 case gets dismissed, right?

7 So that's the double-edged sword, and that's why  
8 Congress and the courts have protected whistleblowers from  
9 these attacks.

10 THE COURT: All right. Well, Mr. Marketos, I'm good  
11 with you. I want to make sure Mr. Wyatt can make his record.

12 Sorry, Mr. Wyatt. Anything further you want to place  
13 on the record? It sounds like you do, and I cut you off for  
14 one question.

15 So what else do you want to tell me about this?

16 MR. WYATT: Two points, just quickly in response to  
17 what we heard.

18 What the cases are talking about is protecting the  
19 ability of the documents to make it to trial. Right? I mean,  
20 that has happened here. There's no motion to exclude.  
21 There's no motion to give us the documents back. There's no  
22 motion to prevent their use at trial. The documents are in.  
23 And so there's nothing -- there's no reason to further prevent  
24 inquiry into how the documents are obtained. That's number  
25 one.

1           And number two, I go back to how these documents in  
2 particular were obtained. The Relators' cases, all of them,  
3 talk about documents that Relators either access as part of  
4 their ordinary job responsibilities or had on a laptop when  
5 they were terminated or left the company. Right? They were  
6 already in possession of the documents.

7           They do not involve situations where the Relator  
8 undertakes sort of deceptive methods to get third parties to  
9 either give or create evidence for use at trial. That is a  
10 different issue, and, frankly, I'm not sure that conduct is  
11 lawful. We're not making that argument, but if we're going to  
12 go to those cases and talk about what's --

13           THE COURT: Well, but that's a good point. You're  
14 saying you don't even know if the statute protects that  
15 conduct.

16           MR. WYATT: I don't know that it does, and I don't  
17 think it does.

18           THE COURT: Well, that goes back to my initial point,  
19 then. I don't have enough before me.

20           So here is where I'm going to leave this. I'm  
21 reserving on this instruction. You guys have some time here,  
22 but I would propose two things. One is you do a little bit  
23 better on the particulars of these facts. I understand that  
24 I've gotten law from both sides, but I need something a little  
25 more particular to this.

1           And two, I will tell you this. Even if I'm inclined to  
2 give some instruction, it needs to be balanced. So the  
3 instruction that's proposed, I absolutely reject. I want to  
4 be very clear about that. But if there's some instruction  
5 that you all want to look to -- because I may be inclined to  
6 give something, but I don't know yet. I haven't seen all the  
7 law, and I want you all to do a little more due diligence on  
8 this -- and, again, by letter, not by brief or anything  
9 formal -- but I want it before the end of trial, maybe in the  
10 next week or so.

11           But consider an instruction that I think at least  
12 indicates the law, that the collection of documents by an  
13 employee, even in violation of a policy that's related to the  
14 lawsuit, is not prohibited. The jury can decide whether the  
15 documents that were shown in this trial and that were seized  
16 by the Relator were related to the case or not. I'm not going  
17 to make an independent ruling, so don't be requesting in  
18 camera review of thousands and thousand of documents. I'll  
19 reject that outright from both counsel. Right?

20           But what I'm saying is try to find a balance in this  
21 proposed instruction that talks about that cleanly but also  
22 doesn't preclude the jury from considering the conduct of the  
23 Relators for other purposes that may be permissible on  
24 cross-examination and impeachment by Janssen.

25           So there's going to be a balance here. And so what I'm

1 telling you is I'm reserving on any instruction for now. I'm  
2 going to give you all a little more time to look at the law to  
3 provide to me and then give me a proposed instruction or two  
4 proposed instructions since this isn't going to be lengthy.  
5 If you can give me a joint instruction where you just have an  
6 objection, that's fine. If they really are so substantively  
7 different, these short instructions, then I'll get one from  
8 Relator and one from Janssen, and then I'm going to review.

9 So even if you're opposed to the instruction,  
10 Mr. Wyatt, Ms. Brown, Mr. Klein, I still want a proposed  
11 instruction from Janssen as an alternative, saying, "Judge, if  
12 you're inclined to disagree with us that no instruction is  
13 necessary, then we believe this one is more appropriate." So  
14 I do still want that from you all, and I want to be clear.

15 MR. WYATT: Understood, Your Honor.

16 THE COURT: All right.

17 So I'm tabling that for now, but I did want to get at  
18 least the argument on there.

19 So when do you all think that you'll give me this  
20 supplement to this issue? In a week or so?

21 MR. MARKETOS: Yes, Your Honor. That would be fine.

22 MR. WYATT: Yes, Your Honor.

23 THE COURT: So I guess next week we're not sitting  
24 Monday; is that correct?

25 MR. MARKETOS: It's the holiday.

1 THE COURT: It's a holiday. The Court's closed.

2 MR. MARKETOS: Yeah. So we could do it by Friday. I  
3 know Your Honor's --

4 THE COURT: Want to do it after the holiday? By  
5 Tuesday of next week I have something from you all?

6 MR. WYATT: That works, Your Honor.

7 THE COURT: All right. Let's do that. By Tuesday.

8 MR. MARKETOS: Very good.

9 THE COURT: Lastly, I don't think this is an issue  
10 that's in contention, but I did get a mini trial brief, just a  
11 brief memo from Relators' counsel just simply saying,  
12 Your Honor, we should be able to cross-examine Janssen  
13 witnesses on Janssen admissions, even if they're not on the  
14 email or, you know, they don't necessarily have personal  
15 knowledge of that.

16 I'm not so sure there's an objection to that, but I  
17 want to hear from you. Mr. Wyatt?

18 MR. WYATT: I think there is a little, Your Honor, so  
19 we'll put in a submission tonight. I don't think it will come  
20 up today.

21 THE COURT: All right. So this is an issue we can  
22 table; it's not coming up in the --

23 MR. MARKETOS: Mr. Mattes is tomorrow, and so we just  
24 want to just make sure it's resolved before he takes the  
25 stand.

1 THE COURT: All right. Give me something later  
2 today, and then we will have this conversation tabled until  
3 tomorrow morning.

4 Fair enough?

5 MR. MARKETOS: Thank you, Your Honor.

6 MR. WYATT: Will do, Your Honor.

7 THE COURT: Is there anything else, then, we need to  
8 chat about?

9 MR. MARKETOS: No, Your Honor.

10 MS. BROWN: I believe there is, actually, Your Honor.  
11 Further to the Court's instruction, we met and conferred  
12 Friday on schedule and sort of where we are. And,  
13 unfortunately, it appears we have very different views of when  
14 the trial should conclude that I think we need to,  
15 unfortunately, put before the Court.

16 THE COURT: Are we not at five and a half weeks  
17 anymore --

18 MS. BROWN: We believe we are, Your Honor, and have  
19 to be, given that we qualified the jury for five or no more  
20 than five and a half. We proposed to Relators at the very  
21 latest the case should close on June 13th, which is the  
22 Thursday of the five and a half weeks. We proposed that,  
23 consistent with the Court's direction, we would not get a  
24 50/50 split of those days, Your Honor, but that Relators would  
25 get 11 days and Janssen would get 8 days and Janssen would

1 begin its case on May 29th.

2 We believe that's consistent with the Court's  
3 directive. It allows for an efficient entry of evidence. And  
4 most importantly, Your Honor, it keeps with what we told these  
5 jurors would be the conclusion of the case.

6 Unfortunately, I think we have very different views of  
7 that. And as I understand from Relators, they are of the view  
8 that the case won't close until the week of June 24th, which  
9 we strongly object to and don't believe that's consistent with  
10 the direction we gave the jury.

11 THE COURT: That's twice as long for trial time.

12 Mr. Marketos, let me hear from you. Is that accurate?

13 MR. MARKETOS: No, Your Honor, it's not.

14 THE COURT: So then let me hear from you on the  
15 record.

16 MR. MARKETOS: Yes. Thank you.

17 We still think, as we have said from the beginning and  
18 during trial, that our case will take 13 -- about 13 days to  
19 try. We have said that, as Your Honor knows, during trial,  
20 before trial. In the joint pretrial order it said 25 days.

21 Your Honor has told the jurors approximately five and a  
22 half weeks when you read that to them, approximately five and  
23 a half weeks. We think that's about right. The thing is if  
24 we have 25 trial days, which was originally what we had both  
25 jointly proposed, just based on counting the days, Your Honor,

1 that puts it at Monday, June 24th.

2 But what I told Ms. Brown is if we have to, we may ask  
3 Your Honor if we can do Fridays because we don't want to  
4 extend the jurors' time in the box beyond five and a half --

5 THE COURT: So if we give Fridays, then what?

6 MR. MARKETOS: Then we're looking at the end of --

7 THE COURT: By the way, guys, I mean, when I ask you  
8 how long a trial is going to be and we're not sitting Fridays,  
9 I ask you all to do the math. I mean, trying to do the math  
10 now to say, Well, Judge, you said to the jury five and a half  
11 weeks, but I also told you all we weren't sitting Fridays. So  
12 this does seem to be a little bit off from what was told to me  
13 at the outset of the case.

14 But that being said, if we are sitting Fridays --  
15 because, look, Janssen needs some time on the case. So how  
16 many days do you have left?

17 MR. MARKETOS: So we will finish -- if we hit 15  
18 days, that's June 6th. That's June 6th. That will be when  
19 we're -- still when we're targeted, still within the same time  
20 frame that we proposed --

21 THE COURT: Yeah, but that's your entire case. No?

22 MR. MARKETOS: It is, but they're putting their case  
23 on, with Janssen witnesses, as our case goes on as well.  
24 They've had 65 percent of the time that we have had.

25 THE COURT: Ms. Brown, how long are you going to need



1 outside of the witnesses that are going to be called anyway  
2 where you're going to be dealing with them when Relators'  
3 counsel calls them?

4 MS. BROWN: Well, when we split out the dates that  
5 remain, 19 days, we gave them 11 and we needed 8. So if  
6 they're increasing from 11, you know, unfortunately, we  
7 probably at least need to cross whoever those additional days  
8 are.

9 I thought the 11 to 8 days, based on what we qualified  
10 the jury for, was consistent with the Court's order that it  
11 wasn't going to be 50/50, and that seemed like a fair and  
12 reasonable way to split the 19 days.

13 MR. MARKETOS: I'm not certain I follow all that.  
14 All I know is this: We have a case that's gone on for 11 and  
15 a half years. We can't get it done in 11 trial days, nor have  
16 we ever insinuated that we could.

17 We can get it done in 14, which would take us to June  
18 6th because we're not sitting on the 5th. And then Ms. Brown,  
19 if she wants additional -- you know, as many additional days  
20 as she needs, all I know is we've had five and a half days of  
21 trial testimony and we need about six and a half -- or excuse  
22 me -- seven and a half more.

23 So I think that takes us through June 6th, Your Honor,  
24 since we're not sitting the 5th or the 27th. And that's --  
25 that's lightning speed for a case of this size.

1 MS. BROWN: Well, Your Honor, I strongly object to  
2 this. I mean, they knew the days going into this when we said  
3 to the jurors -- this is a time when everyone's kids are  
4 getting out from school. When we told the jurors five to five  
5 and a half weeks, we meant that. And we all understood what  
6 that meant for the number of witnesses we could call in our  
7 cases.

8 And if he's talking about taking all the way through  
9 June 6th, even with our eight days, we're going into the week  
10 of the 24th --

11 THE COURT: Yeah. The five and a half weeks takes us  
12 to the week of the 10th, correct?

13 MR. MARKETOS: Yes, Your Honor.

14 MS. BROWN: Yes, Your Honor. And we believe --

15 THE COURT: But if you give up the case on the 6th,  
16 you only have a few days there. Janssen only has a few days.

17 MS. BROWN: I assume he's talking about using all of  
18 the six. So we get the case on the 10th, and we told the  
19 jurors they'd be done by the week before or the 12th. So --

20 THE COURT: Yeah. I was -- I will tell you. My  
21 understanding was the 12th. If you're asking me, based on the  
22 conversations that we've all had, I thought the case goes to  
23 the jury -- well, I was, I guess, optimistic. It would be no  
24 later than the 12th. I'll say it that way, Mr. Marketos, that  
25 the case would go to the jury no later than June 12th. But

1 now you're telling me that you're not going to have the case  
2 done until the 6th, which only gives Janssen two and a half  
3 days --

4 MR. MARKETOS: Your Honor --

5 THE COURT: -- to get the case to them on the 12th.  
6 And if we keep them longer, I have no idea what is going to  
7 happen to this jury.

8 MR. MARKETOS: Your Honor --

9 THE COURT: We just lost a juror today.

10 MR. MARKETOS: I understand. We're going to do  
11 everything we can and then wait for the judgment as a matter  
12 of law filed by Janssen after our case.

13 They have -- they're using a kitchen sink defense, and  
14 we must get our evidence of the elements in. And we have said  
15 that from the beginning, that we need this many days. We said  
16 25. They said, Oh, we can do it in 20. We said, It's not  
17 going to take 20 days. It's going to take 25. We're going to  
18 take 15 days for a case that is this big and has this many  
19 years to cover and this many elements.

20 So this is the squeeze play. It happens. It happens  
21 all the time. And all we're saying is we've been consistent  
22 with how many days we are going to need to put on evidence.

23 THE COURT: So if I add May 31st and June 7th, what  
24 does that do? I can't add this Friday. I literally am the  
25 commencement speaker at a law school. I have to go. I mean,

1 I can't get out of it. So --

2 MR. MARKETOS: That would put us June 3rd and we  
3 pass, because then we -- the reason it was the 6th is because  
4 we're not sitting the 5th. And if we add those two Fridays,  
5 Your Honor, we can get it done on the 3rd instead of the 6th.  
6 And then that gives Ms. Brown -- that would end up totaling, I  
7 guess, 13 and a half days, and then she can end up --

8 THE COURT: Here's what I intend to do. I'm going to  
9 add May 31st and June 7th into the trial schedule, because I  
10 do want the case to get to the jurors somewhere in the time  
11 frame that we told them we were going to do that. And then  
12 that leaves Janssen -- I'm sorry -- that would leave you,  
13 Mr. Marketos -- when would the case handoff go, on the 3rd?

14 MR. MARKETOS: Yeah. I anticipate that we would  
15 finish with our case in chief on June 3rd.

16 I'm sorry, Your Honor, June 4th -- excuse me -- because  
17 we're only adding the 31st --

18 THE COURT: Yeah, the 7th goes to Janssen.

19 MR. MARKETOS: Yes.

20 THE COURT: I added one Friday for the Relators and  
21 one Friday for Janssen. That was by accident, but it seems  
22 fair anyway.

23 MR. MARKETOS: June 4th. Excuse me.

24 THE COURT: Ms. Brown?

25 MS. BROWN: And that contemplates we get the case on

1 the 6th, Your Honor?

2 THE COURT: No, I thought it contemplates you get the  
3 case on the 4th.

4 No, Mr. Marketos?

5 MR. MARKETOS: Yeah. I think we'll be done on the  
6 4th.

7 THE COURT: Ms. Brown, you're going to get the case  
8 on the 4th, and a chunk of your witnesses are being called by  
9 Relators' counsel. This is the best I'm going to be able to  
10 do, but I don't think it prejudices you.

11 MS. BROWN: Well, Your Honor, just so I'm clear, I  
12 think it means we start our case on the 5th, and we would  
13 have -- no, he's saying -- oh, the 5th is dark. So we start  
14 the case on the 6th. We would have the 6th, the 10th, the  
15 11th, the 12th, and the 13th.

16 MR. MARKETOS: And the 7th.

17 MS. BROWN: And the 7th. So that's seven days to  
18 their 13 and a half. And you're contemplating closings on the  
19 10th?

20 MR. MARKETOS: No.

21 THE COURT: No, no. Hold on. So 6, 7, 10, 11, 12.  
22 Right? If we do part of 13, fine. But shouldn't you be able  
23 to close on the 13th?

24 MS. BROWN: Well, Your Honor, but that gives us five  
25 days to their 13 and a half. I mean, that's -- they're

1 getting almost triple the time. I understand the Court didn't  
2 want to do 50/50, and I'm not pushing back on that, but five  
3 to 13 and a half seems enormously unfair.

4 THE COURT: So what if we gave you the 13th?

5 MS. BROWN: They're still getting more than double.

6 THE COURT: It's their case, Ms. Brown. And a lot of  
7 your witnesses are being called.

8 MS. BROWN: But that's not true, Your Honor. We've  
9 only had one witness of ours called in their case. They're  
10 putting on multiple witnesses who are --

11 THE COURT: Ms. Brown, you're the defender of this  
12 jury. Right? And if they can't be here that long, you want  
13 me to cut the Relators' case with the burden of proof in the  
14 trial? That, I'm not going to do for you either.

15 So which one is it? Because you raised this issue with  
16 the Court --

17 MS. BROWN: Correct.

18 THE COURT: -- not Relators' counsel. And you raised  
19 it to be what about the children? And what about the schools?  
20 Okay. I'll listen to what you have to say. But now what  
21 you're saying is the answer to this is to cut the knees off  
22 Relators' counsel presenting their case when they have the  
23 burden of proof. That, I won't do for you.

24 So if you want me to bend, I'm bending, folks, and I'll  
25 compromise. And if this wants to be an appellate issue for

1 you all, good luck with it. But I'm going to extend the trial  
2 times so that we can get this jury out somewhere in the time  
3 frame that we told them and not prejudice you with your  
4 defense.

5 But if I give you until the 13th, then you all can  
6 close on the 14th, get the case to the jury at least that  
7 week. We're a few days late to the jury, but that's life.

8 MS. BROWN: Your Honor, may I be heard on one other  
9 issue with that schedule?

10 THE COURT: Yes.

11 MS. BROWN: We had indicated to Relators that we have  
12 a doctor. We moved the doctor we had for the 23rd. I  
13 understand that's this week. We're nowhere near our case. We  
14 do have a doctor for a very, very short exam on the afternoon  
15 of the 30th that we would ask to take out of turn if this is  
16 the schedule.

17 THE COURT: Mr. Marketos?

18 MR. MARKETOS: Your Honor, that's fine. It's really  
19 not, but it's fine in that I think they're saying this doctor  
20 only has one day that he can testify.

21 But, you know, we obviously need him here, and my  
22 understanding is that they're saying they want this doctor to  
23 testify on that day and by video because he's got an issue  
24 with his mother-in-law's health, as I understand it.

25 THE COURT: Well, let me hear all the details then,

1 because you're not giving me much there.

2 So you have a physician that you want to testify on the  
3 30th, which is still on the Relators' case, but this physician  
4 has some unavailability issue because of what?

5 MS. BROWN: Your Honor, we understand there to be  
6 sort of a family health issue with his mother-in-law, who, I  
7 believe, is very close to passing. And so he has offered --  
8 he very much wants to participate, is willing to participate,  
9 but for family reasons needs to do it remotely.

10 THE COURT: All right. And you all lived with this  
11 schedule, but I have to put this witness on the 30th.

12 MS. BROWN: Yes. With the Court's permission, yes,  
13 because then -- I think his direct will be 30 minutes.

14 THE COURT: All right. I'll do it. But, Ms. Brown,  
15 then you have to get on board with the Court's new proposal to  
16 add all these Fridays in and you getting the case on the 6th  
17 and being done by the 13th and closing on the 14th.

18 MS. BROWN: I understand the Court's ruling,  
19 Your Honor.

20 THE COURT: All right. Mr. Marketos?

21 MR. MARKETOS: That's fine, Your Honor.

22 THE COURT: So we will let that witness go on the  
23 30th?

24 MR. MARKETOS: All right.

25 THE COURT: All right. Folks, I'm not moving from



1 this schedule because this is already extended beyond, I  
2 believe, in good faith what the counsel provided to the Court.  
3 This was not my understanding when we were building the five  
4 and a half weeks that's what this jury was informed, and now  
5 we're taking them to the end of that week, which is already  
6 extending beyond, and then they have time for deliberations.  
7 So I'll deal with that in good time, but that's not something  
8 I'm going to drop on the jury today, but I will tell you all  
9 that this is the schedule. So on the 6th they start no matter  
10 what's going on here.

11 And if there are issues with delay or things like that  
12 where we have to move things forward, then let me know because  
13 I'll get involved. But that's where we are.

14 So what else do we have to talk about before we find  
15 the rest of these jurors and get back to witness testimony?

16 Mr. Marketos?

17 MR. MARKETOS: That's all from the Relators,  
18 Your Honor. Thank you.

19 THE COURT: Ms. Brown?

20 MS. BROWN: Nothing. Thank you, Your Honor.

21 THE COURT: All right. So -- but we're all clear on  
22 the trial schedule, correct? Relators' counsel, you're  
23 closing this case on the 4th. You have a day break on the  
24 5th. Janssen will have the beginning, starting on the 6th,  
25 not the afternoon of the 6th, not at 3 o' clock. Their

1 morning starts. They hit the ground running on the 6th, and  
2 then we go through until the 13th.

3 MR. MARKETOS: Yes, Your Honor. Right.

4 THE COURT: And then the 14th I think we have  
5 closings and instructions and deliberations. Does that make  
6 sense?

7 MR. MARKETOS: Yes, Your Honor.

8 THE COURT: Ms. Brown?

9 MS. BROWN: I mean, I understand the Court's ruling,  
10 Your Honor. I hear you.

11 THE COURT: But I don't know what that means. Does  
12 that mean that you're objecting to the trial schedule even  
13 though I'm putting your witness on the 30th when I don't need  
14 to do that?

15 MS. BROWN: I appreciate that, Your Honor, but as I  
16 understand it, I am objecting to the fact that we're not  
17 getting the case before the 6th. But I am not going to  
18 continue to argue with the Court. I hear the ruling, and we  
19 will make it work.

20 THE COURT: All right.

21 MS. BROWN: I would request that we get the case on  
22 the 4th, but I have heard the Court, and I don't want to  
23 argue.

24 THE COURT: I will say this. If anything happens on  
25 the 4th where we close the Relators' case sometime earlier, be

1 prepared, because I won't say, Well, I told you on the 6th.  
2 We can start on the 4th. So I'm not going to prohibit you  
3 from getting it on the 4th. What I'm saying is it's no later  
4 than they complete their case on the 4th. Then if for some  
5 reason we get through the witnesses and it goes faster than we  
6 anticipated, you will start on the 4th.

7 Fair enough?

8 MS. BROWN: I understand.

9 THE COURT: All right. That's where we are.

10 Folks, nothing further this morning?

11 MR. MARKETOS: No, Your Honor.

12 MS. BROWN: I understand there's one issue,  
13 Your Honor. There's a technical issue with the system being  
14 off. I know Phil was trying to help, but I'm not sure it's  
15 resolved.

16 THE COURT: Let's -- sorry, folks. We're going to  
17 take a five-minute recess. I think the IT department -- no,  
18 you guys can be seated. The IT department wants to work on  
19 this. Let's take a few minutes.

20 And then where are we? Where are we starting on the  
21 trial?

22 MR. MARKETOS: I think as I understand it, they're  
23 finishing the cross-examination of Ms. Brancaccio, which was  
24 carried over the weekend.

25 Mr. Wirmani is going to do some redirect, and then

1 we're going to have Dr. Glatt, our medical -- our clinical  
2 expert is going to take --

3 THE COURT: Do we think we'll have more witnesses  
4 beyond the doctor?

5 MR. MARKETOS: Uh --

6 THE COURT: We'll see. But you have them ready?

7 MR. MARKETOS: Yes, Your Honor. They are here.

8 THE COURT: All right. Once we get IT ready, before  
9 I get the jurors, though, have Ms. Brancaccio back in the  
10 witness stand, since she's already on cross.

11 MR. MARKETOS: Yes, Your Honor.

12 MS. BROWN: And, Your Honor, just one procedural  
13 question, since this is the first expert. Does the Court  
14 provide an opportunity to voir dire on qualifications before  
15 accepting the qualifications, or is that just saved for cross?

16 THE COURT: No -- so you have some questions that you  
17 want to put on the record regarding the background of this  
18 expert, like, as far as voir dire?

19 MR. MARKETOS: Your Honor already ruled on --

20 THE COURT: Unless -- is there a motion that I've  
21 already addressed on this expert?

22 MR. MARKETOS: Yes. He is one of the Daubert -- you  
23 ruled on the Daubert on all of these experts and this --

24 THE COURT: Ms. Brown, is this a Daubert motion on  
25 this particular expert?

1 MS. BROWN: There was, and he was excluded in part.  
2 But sometimes you're permitted to voir dire on qualifications  
3 before the Court accepts what's been proffered from this  
4 expert.

5 THE COURT: But I've already decided he's an expert  
6 for purposes of the case in chief?

7 MR. MARKETOS: Yes, Your Honor.

8 THE COURT: Let me finish because -- let me finish  
9 because --

10 MR. MARKETOS: I'm sorry.

11 THE COURT: Let me just finish what I'm saying. Did  
12 I already decide this person was an expert, can testify as an  
13 expert in the trial?

14 MR. MARKETOS: Yes, Your Honor.

15 THE COURT: So, Ms. Brown, I don't see how it's  
16 necessary there. I would allow you to do it if I didn't have  
17 it as part of one of my motions in limine.

18 But if I've already ruled on it, then I think that's a  
19 wasted exercise, and I'll deny that request.

20 All right. Folks, we're in recess. Feel free to be  
21 seated. Let me get IT in. Thank you.

22 (Brief pause.)

23 THE COURT: Just so we're clear, so I had -- correct  
24 me if I'm wrong, I had -- Janssen had the case the 13th.  
25 Closings were the 14th; is that right?

1 MR. MARKETOS: Yes, Your Honor.

2 THE COURT: Janssen gets the case until the end of  
3 the week. They get the case on the 14th. Closing starts the  
4 following week because the Court has a conflict on the 12th  
5 that I just did not register.

6 So everything remains exactly the same except for  
7 Janssen will just have the case that one additional day, which  
8 I actually don't think is unhelpful to the jury. It's the end  
9 of the week. You guys finish. They get a breath on the  
10 weekend, and you guys close, and then you get the case fresh  
11 with instructions and closings.

12 And just as a reminder, I'm going to give the final  
13 instructions before closing, so that when they deliberate, the  
14 closings are fresh in their mind. They're not listening to  
15 45 minutes of me regurgitating final instructions.

16 So that's the one change I wanted to make to the trial  
17 schedule. Other than that, absent something that's  
18 unforeseeable -- if there is something unforeseeable, folks,  
19 let me know sooner rather than later, but right now that's the  
20 best I think we can do for you all and keeping this jury  
21 intact.

22 The last thing I want is to lose four more jurors, and  
23 we're all back to doing this in a month because that's what's  
24 going to happen if we lose any more folks.

25 So with that, anything more?

1 MR. MARKETOS: Your Honor, I'm sorry. Just this  
2 Thursday, you had a half day -- we have a half day this  
3 Thursday. That's still happening, right? I just want to make  
4 sure.

5 THE COURT: Cancel out. We got rid of it. Yeah, so  
6 this Thursday, we moved that conflict. You can have the full  
7 day.

8 MR. MARKETOS: Full day. Thank you.

9 THE COURT: So maybe that helps, too. Yep. That one  
10 we were able to fix.

11 MR. MARKETOS: All right. Thank you, Your Honor.

12 THE COURT: Anything else?

13 MR. MARKETOS: No, Your Honor.

14 THE COURT: Is Ms. Brancaccio --

15 MR. MARKETOS: Yes, she is here.

16 THE COURT: Why don't we have her come back on.

17 Let's get the jurors. Folks, I'm also going to alert  
18 the jurors -- because they're going to recognize that Juror  
19 Number 2 is not here, so I'm going to give a brief instruction  
20 so they're not like confused about what is going on. All  
21 right.

22 THE DEPUTY COURT CLERK: All rise.

23 (Jury enters the courtroom.)

24 THE COURT: All right, folks. Everybody have a seat.  
25 Welcome back, jurors. I hope you had a good weekend.

1 Just one brief -- Juror Number 2 is no longer with us,  
2 and I'll just tell you she suffered from a severe or a serious  
3 family tragedy yesterday. I excused her this morning after  
4 speaking with counsel.

5 So Juror Number 2 is no longer going to be with us. So  
6 basically all your numbers switch after Juror Number 1. You  
7 become 2, 3, 4, 5, 6, 7, 8, 9, right?

8 So we have nine jurors. Your number is just pushed up  
9 one, and you can keep that seat open if you like. However,  
10 if, you know, you're comfortable where you've been sitting,  
11 that's fine. But I just wanted to make sure you knew so  
12 you're not thinking, Well, what happened to our -- our juror?

13 So she's going to be excused. She is doing all right.  
14 But I wanted to make sure you knew why I let her out of the  
15 trial.

16 So other than that, we're going to continue with  
17 witness testimony this week.

18 One quick reminder, just because if you're thinking  
19 about next week, Monday is a holiday. It's Memorial Day  
20 weekend. This courthouse is closed, so whether I wanted to  
21 push you to do the trial on Monday, I cannot.

22 You do have Monday off, just trying to remind you guys  
23 when the Court has a conflict or when you're not going to be  
24 sitting for trial, so we're going to be proceeding until  
25 Thursday of this week.



1 And then you'll have Friday and Monday away from trial,  
2 and then we'll reboot Tuesday.

3 So with that, Ms. Brown, are you ready to continue  
4 cross-examination with Ms. Brancaccio?

5 And, Ms. Brancaccio, as a reminder, you're still under  
6 oath from last week.

7 THE WITNESS: Yes, Judge.

8 THE COURT: All right.

9 MS. BROWN: May I proceed, Your Honor?

10 THE COURT: You may.

11 MS. BROWN: Thank you very much.

12 (**CHRISTINE BRANCACCIO**, HAVING BEEN PREVIOUSLY DULY

13 SWORN/AFFIRMED, TESTIFIED AS FOLLOWS:)

14 (CROSS-EXAMINATION BY MS. BROWN:)

15 Q. Good morning, Ms. Brancaccio.

16 A. Good morning.

17 MS. BROWN: And good morning, jurors.

18 BY MS. BROWN:

19 Q. I'm going to try and be as efficient as possible with the  
20 remainder of your cross this morning, ma'am, and move through  
21 a number of topics pretty quickly.

22 Okay?

23 A. Okay.

24 Q. So let's just reorient where we were on Friday when we  
25 left off.

1 MS. BROWN: Could I have the ELMO, please, Mr.

2 Knecht. Thank you.

3 BY MS. BROWN:

4 Q. When we left on Friday, we had been talking about some of  
5 your efforts to help the lawyers get folks to sign  
6 declarations that would help your case.

7 Do you remember that, ma'am?

8 A. I remember.

9 Q. And we looked at this graphic, and I think you corrected  
10 me that Ms. Porter was not part of the New York district.

11 Is that right?

12 A. Correct.

13 Q. But other than that, this graphic reflects the people  
14 that you worked side by side with during the time period that  
15 you were a sales rep in the New York district.

16 Correct?

17 A. This was a combination of New York 1 and New York 2.

18 Q. Sure.

19 And you did not work to obtain declarations from any of  
20 these folks.

21 Correct?

22 A. I did not.

23 Q. Okay.

24 And do you know the number of people who received  
25 outreach to sign a declaration and declined to do that?

1 A. I don't know.

2 Q. All right.

3 The other thing that you told us on Friday was that you  
4 called on hundreds of health care providers.

5 Do you recall that, ma'am?

6 A. Yes.

7 Q. All right.

8 And here's a list of some of those providers that  
9 appeared on your call notes. It goes from 2013 and 2014.

10 Do you see that, ma'am?

11 A. Yes.

12 Q. And as far as you know and in terms of your efforts to  
13 get people to sign up declarations, you don't have  
14 declarations from any of these hundreds of doctors that you  
15 claim you were delivering off-label messages to for many, many  
16 years.

17 Correct?

18 A. To the best of my knowledge, no.

19 Q. Well, sitting here today, you don't have a declaration  
20 from any doctor to support the claims that you made to our  
21 jury.

22 Correct?

23 A. That would be correct.

24 Q. And one of the things you do know is that doctors, at  
25 least by 2010, were required by the FDA to report if somebody

1 was in their office promoting off-label in the way you  
2 described.

3 You know that, right, ma'am?

4 A. If they knew we were promoting off-label, I would agree  
5 with that.

6 Q. All right.

7 MS. BROWN: Let's take a look, if we could, at  
8 tab 40, D-8659.

9 Permission to admit and publish.

10 MR. WIRMANI: No objection, Judge.

11 THE COURT: All right. So admitted.

12 MS. BROWN: Thank you, Your Honor.

13 (Defendants' Exhibit 8659 in evidence.)

14 BY MS. BROWN:

15 Q. If we take a look here, this is an email from Tony Dolisi  
16 back in 2010.

17 Do you see that, ma'am?

18 A. Yes.

19 Q. All right.

20 And Tony Dolisi, just to orient us, he was your manager  
21 in New York for a period of time.

22 Correct?

23 A. That's right.

24 Q. Is it your testimony that he instructed you to promote  
25 off-label?

1 A. Yes, it is.

2 Q. All right.

3 So here's Mr. Dolisi emailing your team, who includes  
4 yourself, obviously.

5 Right?

6 A. Yes.

7 Q. Back in 2010.

8 And what he says is, "Please read this important  
9 message about a new FDA program."

10 Do you see that?

11 A. Yes.

12 Q. All right.

13 He says, "Please be aware, and as always, stay  
14 on-label."

15 Do you see that?

16 A. Yes, I do.

17 Q. And your testimony to our jurors is he didn't really mean  
18 this?

19 A. Well, what was in written form and what was told to us  
20 verbally were entirely two different things.

21 Q. And so what he says here and what he includes below is  
22 the new program that asked physicians to report any misleading  
23 advertisements or off-label promotion.

24 Right?

25 A. Yes, I see that.

1 Q. And you were aware of that.

2 Right?

3 A. Yes, ma'am.

4 Q. And as part of this program, the FDA actually trained  
5 physicians about how to identify misleading sales aids.

6 You knew that, right, ma'am?

7 A. I see it.

8 Q. Yep.

9 A. I see it here, yeah.

10 Q. All right.

11 And in addition, the agency, that's the FDA, simplified  
12 the way doctors could report any off-label activity by having  
13 a hotline and an email to encourage doctors to do that.

14 Right?

15 A. I see that written, yes.

16 Q. And you're not aware, as it relates to this case, of any  
17 complaint of any single doctor in the United States that would  
18 corroborate the activities that you described to our jury last  
19 week.

20 Correct?

21 A. That's correct, because I don't believe that they knew  
22 when we were talking to them off-label.

23 Q. Okay.

24 Your testimony is the doctors did not understand that  
25 the information you were providing is -- was different than

1 the label?

2 A. Yes.

3 Q. Okay.

4 Let's talk about some of that information.

5 Okay, ma'am?

6 A. Sure.

7 Q. So you allege in this lawsuit that you promoted Intelence  
8 to treatment-naive patients.

9 Right?

10 A. Correct.

11 Q. And our jurors already heard a bunch about naive and  
12 experienced, but generally, an indication for a medicine could  
13 be for people who have already used a medicine before.

14 Right?

15 A. Yes.

16 Q. Like an experienced patient --

17 A. Treatment-experienced.

18 Q. Treatment-experienced, right?

19 Or the other term is "treatment-naive," somebody who  
20 hasn't yet had any medicine.

21 Right?

22 A. Correct.

23 Q. All right.

24 And your allegation in this case is that, even though  
25 Intelence was only approved for treatment-experienced, you

1 nevertheless promoted it for treatment-naive.

2 Correct?

3 A. Yes.

4 Q. And were you here when Donna Graham testified? Were you  
5 sitting in the courtroom?

6 A. Yes, I was.

7 Q. And you heard Ms. Graham testify she never heard anybody  
8 promote Intelence in treatment-naive.

9 Did you hear that?

10 A. I'll say okay. I don't really recall it right this  
11 second, but...

12 Q. All right.

13 And the fact of the matter is these treatment-naive  
14 claims, they sort of got added later on to your lawsuit.

15 Right, ma'am?

16 A. No. I disagree with that.

17 Q. Well, I mean, you've had a little trouble keeping track  
18 of the treatment-naive allegations.

19 Right, ma'am?

20 A. I'm not sure what you mean.

21 Q. For example, we asked you at your deposition about your  
22 promotion of Intelence.

23 You recall that, right, ma'am?

24 A. Yes.

25 Q. And you said that the only off-label promotion that you



1 engaged in for Intelence was once a day.

2 Do you remember that?

3 A. Yes, I do.

4 Q. And then something interesting happened.

5 Right?

6 A. I don't know. What?

7 Q. You took a break, right, which happens sometimes in  
8 depositions.

9 Right?

10 A. Sure.

11 Q. And our jury's already heard all about depositions, but  
12 it's where lawyers can ask questions of witnesses under oath.

13 Right?

14 A. Yes.

15 Q. All right.

16 So you were asked under oath about what off-label  
17 statements did you make about Intelence, and you said, "The  
18 only statements I made were about once a day."

19 Right?

20 A. Yes, I did say that.

21 Q. And then you took a break, and you came back, and you  
22 changed your testimony.

23 Right?

24 A. I added to it.

25 Q. Right.

1 And we said, Well, that's strange. We just asked you  
2 this question. What happened?

3 And you told us you had spoken with your lawyers.

4 Right?

5 A. I did not say that. I said that I went -- we went on a  
6 break, and I was -- I was talking to them but not about that.  
7 It hit me that I forgot that piece of it.

8 As you can imagine, a deposition is very stressful, and  
9 I did -- I left that piece out before we went on break.

10 Q. The question we asked you, ma'am, was, if during that  
11 break you had spoken to your lawyers, and the answer was  
12 "Yes."

13 A. Yes.

14 Q. Right?

15 And then after having spoken to your lawyers, you came  
16 back and remembered Intelence in treatment-naive.

17 Correct?

18 A. I remembered it on my own, and I believe I said that in  
19 the deposition.

20 Q. You said in the deposition you had discussed it with your  
21 lawyers.

22 Right, ma'am?

23 A. I don't recall the exact words.

24 Q. Okay.

25 Let's take a look at it, then, please.

1 MS. BROWN: Your Honor, permission to play the  
2 deposition testimony.

3 THE COURT: Any objection?

4 MR. WIRMANI: What is the line and page?

5 MS. BROWN: It would be 256/23 to 259/6.

6 MR. WIRMANI: Your Honor, that's fine, but under the  
7 rule of optional completeness, we ask that the deposition be  
8 played through page 259, line 9.

9 THE COURT: Well, Ms. Brown doesn't have to play it.  
10 Are you saying you want to play it on redirect?

11 MR. WIRMANI: We can do it that way as well,  
12 Your Honor.

13 THE COURT: Ms. Brown, any objection to that?

14 MS. BROWN: No objection.

15 THE COURT: All right. I'm not going to direct her.  
16 She can play what she wants, but if you want the rest in  
17 later, you can do it on redirect.

18 MS. BROWN: May I proceed with that, Your Honor?

19 THE COURT: You may.

20 MS. BROWN: Can we play, Mr. Knecht, 256/23 through  
21 259/6?

22 (Video clip is played at this time.)

23 BY MS. BROWN:

24 Q. Ma'am, we spoke last week a little bit about the speaker  
25 program.

1 Do you remember that?

2 A. Yes.

3 Q. And we looked at an email from your lawyers where they  
4 were reaching out to you about maybe adding some claims about  
5 the speakers to the complaint.

6 Do you remember that?

7 A. Yes. Excuse me. Yeah.

8 Q. All right.

9 And to be clear, though, there's a lot of information  
10 about Janssen's speaker program that you're not familiar with.

11 Fair enough?

12 A. I guess that's fair, yeah.

13 Q. For example, you don't know Janssen's criteria for  
14 selecting speakers to be part of the bureau.

15 Correct?

16 A. I know what I was told.

17 Q. You don't know if there are academic degrees or  
18 credentials that are considered as part of the selection  
19 process.

20 Correct, ma'am?

21 A. I would think that there's some academic -- you just  
22 can't take anybody off the street to speak, so...

23 Q. In terms of the criteria that's set out, the eight  
24 different numbered factors that the committees consider to be  
25 fair, you're not familiar with those.

1 Right, ma'am?

2 A. Not all of them, no.

3 Q. And on one occasion, you did propose prescribers to be  
4 part of the speakers' bureau.

5 Right?

6 A. Yes.

7 Q. And none of those prescribers that you proposed made it  
8 on to the bureau.

9 Correct?

10 A. To the best of my knowledge, no.

11 Q. And as a sales representative, you could request that a  
12 speaker program be held.

13 Correct?

14 A. Yes.

15 Q. But you don't know who approved that request when you  
16 made it.

17 Correct?

18 A. Correct.

19 Q. And you weren't involved in training the speakers that  
20 presented at the programs.

21 True?

22 A. No, I was not.

23 Q. You weren't involved in preparing the speakers to present  
24 at a program.

25 True?

1 A. That's true.

2 Q. And even though you've made a lot of allegations about a  
3 lot of speaker programs, to be fair, you don't know what  
4 happened at speaker programs that you didn't personally  
5 attend.

6 Correct?

7 A. That's not entirely true because Nancy Bartnett -- if it  
8 was a speaker in the New York area that Nancy Bartnett had  
9 responsibility for, she would tell us about that speaker  
10 program, and she would -- she would rant to us about how well  
11 the speaker did and so on.

12 Q. And I want to talk about Nancy Bartnett today for sure.

13 A. Okay.

14 Q. But my question is: As it relates to speaker programs  
15 that you didn't attend, you don't know what was presented at  
16 those programs, right, ma'am?

17 A. No. I can only tell you what she told me.

18 Q. Okay.

19 MS. BROWN: Let's look at -- permission to play  
20 293/21 to 294/4.

21 MR. WIRMANI: Your Honor, I don't see any  
22 inconsistencies between what she is trying to play and --

23 THE COURT: Sidebar.

24 (Sidebar begins at 10:09 a.m.)

25 THE COURT: Remind me of the question, Ms. Brown.

1 MS. BROWN: You don't know what happened on speaker  
2 programs you didn't attend, and she says, I don't know, I  
3 wasn't there.

4 THE COURT: I thought --

5 MS. BROWN: She said, Nancy Bartnett told me that  
6 happened. She said she has --

7 THE COURT: She said, I wasn't there. I only know  
8 what Nancy told me.

9 MS. BROWN: Right. That wasn't her answer. I don't  
10 know what was presented. She doesn't say, I know from Nancy  
11 Bartnett.

12 THE COURT: Well, it's the same answer, right? You  
13 said, You have no personal knowledge, right?

14 MS. BROWN: Yep.

15 THE COURT: So she's testifying under oath that "I  
16 have no personal knowledge of what happened. My only  
17 knowledge" -- which is hearsay -- "is what somebody told me."

18 MS. BROWN: But she tried -- she says, I don't know  
19 what was presented there. She doesn't give another source of  
20 the information --

21 THE COURT: All right. So are you going to say --  
22 then why not -- why not just ask her and say, You didn't  
23 mention Nancy Bartnett told you anything during your  
24 deposition, correct?

25 MR. WIRMANI: You can just ask her --

1 THE COURT: Stop. You've got to stop doing that  
2 because of the court reporter, and I'm talking.

3 You can ask her -- why don't you ask her, You mentioned  
4 to Ms. Bartnett during your deposition, and then if she says  
5 something inconsistent with that, then you can play that.  
6 Then I think you're okay.

7 MS. BROWN: Okay.

8 THE COURT: All right.

9 (Sidebar was concluded at 10:10 a.m.)

10 (Open court.)

11 MS. BROWN: May I proceed, Your Honor?

12 THE COURT: Yes, you may.

13 MS. BROWN: Thank you.

14 BY MS. BROWN:

15 Q. And, Ms. Brancaccio, when we asked you at your deposition  
16 if you knew what happened at programs you didn't attend, you  
17 said you didn't.

18 Correct?

19 A. If I said that in my deposition, then I'll agree with  
20 that.

21 Q. And speakers are compensated for their time presenting at  
22 these programs.

23 Correct, ma'am?

24 A. Yes.

25 Q. And that's sometimes known in the documents as an



1     honorarium.

2             Correct?

3     A.    Yes, ma'am.

4     Q.    All right.

5             And you allege that speakers were paid a higher  
6     honorarium or a higher amount of money if they were  
7     prescribing more.

8             Correct?

9     A.    Yes.

10    Q.    But you actually don't know how Janssen determined the  
11    honorarium that speakers would receive.

12             Correct?

13    A.    That would be correct.

14    Q.    And you don't know how fair market value was determined  
15    for the speaker compensation or honorarium.

16             Correct?

17    A.    That would be right, yeah.

18    Q.    You do know that there is a cap on how much a speaker  
19    could be compensated per program.

20             Correct?

21    A.    Yes.

22    Q.    And you do know that there was a limit on the number of  
23    speaker programs an individual could perform.

24             Correct?

25    A.    I know that, yes, and sometimes that provider was able to

1 get that cap lifted per year.

2 Q. We looked, ma'am, last week at a document that's already  
3 in evidence.

4 MS. BROWN: If I can have the ELMO.

5 BY MS. BROWN:

6 Q. You reached out to a third party called MedForce to try  
7 and get some information on speakers.

8 Correct, ma'am?

9 A. Correct.

10 Q. And you reached out in 2012, a few months before your  
11 lawsuit.

12 Correct?

13 A. I did.

14 Q. And you asked for speaker data a number of years in the  
15 past.

16 Correct?

17 A. I did.

18 Q. 2009, 2010.

19 Correct?

20 A. Yes, ma'am.

21 Q. And the speaker data you asked for included speakers that  
22 were outside of your territory.

23 Right, ma'am?

24 A. Yes.

25 Q. Included information on nationwide speakers.

1 Correct?

2 A. Yes.

3 Q. You didn't have a business purpose at Janssen in 2012 to  
4 look at old speaker data around the country that was three  
5 years old.

6 Correct?

7 A. No, there was no business purpose.

8 Q. No business purpose.

9 The purpose was the lawsuit.

10 Yes, ma'am?

11 A. Yes.

12 Q. And you got access to data about speakers that you  
13 wouldn't have otherwise had because they were outside of  
14 New York.

15 Correct, ma'am?

16 A. Yes.

17 Q. And you got access to data about the amount of money  
18 those speakers had been paid.

19 Correct?

20 A. Yes.

21 Q. And that, too, was data you would not otherwise have had  
22 access to in the New York region.

23 Correct, ma'am?

24 A. Right.

25 Q. That's data that you asked MedForce to give you for

1 purposes of using in a lawsuit.

2 True, ma'am?

3 A. Yes. That's true.

4 Q. Now, you claim you were being pressured to promote  
5 off-label for many years.

6 Correct?

7 A. That's correct.

8 Q. And you know as a Janssen employee that if that were  
9 true, you had an obligation to report that.

10 Right, ma'am?

11 A. Yes.

12 Q. All right.

13 And before filing this lawsuit, you actually reminded  
14 Ms. Penelow about your obligation to report, didn't you?

15 A. I don't recall.

16 MS. BROWN: Tab 15, Your Honor. Permission to admit  
17 D-6025.

18 MR. WIRMANI: No objection, Judge.

19 THE COURT: All right. So admitted.

20 (Defendants' Exhibit 2065 in evidence.)

21 BY MS. BROWN:

22 Q. Ms. Brancaccio, we have looked throughout my questioning  
23 here at a number of emails that you forwarded from your  
24 Janssen work account to your personal account.

25 Correct?

1 A. Yes, we have.

2 Q. And you did that in connection with your lawsuit.

3 Right, ma'am?

4 A. Yes.

5 Q. You were collecting up evidence for your lawsuit.

6 Correct?

7 A. Probably among other things, yeah.

8 Q. Well, what were the other things?

9 A. I don't know. Maybe my numbers. Just to keep track of  
10 my sales numbers.

11 Q. But, like, that speaker stuff we just looked at, that had  
12 nothing to do with your numbers or your job.

13 Right?

14 A. No.

15 Q. Okay.

16 You went to a third party to get data you otherwise  
17 wouldn't have had access to.

18 Correct?

19 A. Yes.

20 Q. And you did that for purposes of a lawsuit.

21 True?

22 A. I already said that, yes.

23 Q. All right. And so here is another email that starts --  
24 this is, again, just to orient us, up at the top, this is  
25 February of 2012, and you filed your lawsuit in December of

1 2012.

2 Right, ma'am?

3 A. Yes.

4 Q. All right.

5 So this is prior to your lawsuit, and you send --  
6 actually, here you're sending it to Ms. Penelow.

7 Correct?

8 A. That's correct.

9 Q. And you tell her, "Found this."

10 Do you see that?

11 A. Yes.

12 Q. And what you found was information about improvements to  
13 Janssen's hotline.

14 Right?

15 A. Yes.

16 Q. All right.

17 What you found and what you sent to Ms. Penelow before  
18 you filed the lawsuit was an email alerting everyone in the  
19 field to the launch of a new global hotline in February of  
20 2011.

21 Right?

22 A. Yes.

23 Q. And what it talks about here is that J&J was going to be  
24 launching an improved hotline --

25 A. All right.

1 Q. -- for a family of companies, including Janssen.

2 Right, ma'am?

3 A. Yes, I see that.

4 Q. All right.

5 And it would be managed by a third-party vendor.

6 Correct?

7 A. Yes, that's what it says.

8 Q. All right.

9 And that's kind of like the third-party vendor

10 MedForce. Like, sometimes for compliance reasons, you know,

11 Janssen uses third parties to run things like speaker programs

12 and hotlines and things like that.

13 Right?

14 A. Yes, they use those third parties.

15 Q. All right.

16 And what this email that you reminded yourself about

17 said is "Employees are encouraged to report any prohibited or

18 unlawful activities of which they are aware."

19 Right?

20 A. Right.

21 Q. And "The company will not tolerate threats or acts of

22 retaliation against individuals who in good faith provide

23 information in connection with reports of potential

24 misconduct."

25 Do you see that?

1 A. I see it.

2 Q. All right.

3 "Disciplinary action will be taken against any employee  
4 who retaliates against others who report such violations."

5 Do you see that?

6 A. I do.

7 Q. And it says, "Disciplinary action could include  
8 termination."

9 Right?

10 A. It does say that.

11 Q. Yeah.

12 So what you sent to Ms. Penelow, several months before  
13 you filed this lawsuit, was a reminder from Janssen about some  
14 of the many ways that Janssen has for people to report the  
15 conduct that you've complained about in this lawsuit.

16 Right?

17 A. Right. And she did report it.

18 Q. And we're going to talk to her about what she reported  
19 for sure. But I want to talk to you about what you did.

20 Okay, ma'am?

21 A. Sure.

22 Q. All right.

23 And by the way, are you under the impression that  
24 Ms. Penelow reported this conduct that you're claiming in this  
25 lawsuit?



1 A. Yes, I am.

2 Q. Why do you think that?

3 A. Because I know it.

4 Q. Tell me how.

5 A. I know she reported it to human resources. I know that  
6 she reported it to -- verbally to our immediate supervisors,  
7 several times.

8 Q. And do you know that because Ms. Penelow told you that?

9 A. Yes.

10 Q. All right.

11 So back to this. What J&J reminded its field of in  
12 this email that you forwarded to Ms. Penelow is that it  
13 doesn't tolerate people retaliating against people who are  
14 reporting improper conduct.

15 Right?

16 A. That's right.

17 Q. And that, in fact, it would fire -- disciplinary action  
18 would be taken, including terminating people who retaliate  
19 against people who are raising their hand and reporting  
20 compliance issues.

21 Right, ma'am?

22 A. Yes.

23 Q. And so when you forwarded this to Ms. Penelow, you sort  
24 of had a choice, right, in February of 2012.

25 Correct?

1 A. I don't know where you're going. A choice?

2 Q. Well, you could have called that hotline if these things  
3 were really happening and you could have reported it.

4 Right?

5 A. Well, these things do really happen. They did really  
6 happen. I know that she reported it. I know another woman in  
7 New York 2, Joanne Sario reported it. I saw the -- I saw what  
8 happened to them as far as how their day-to-day jobs went, and  
9 Joanne Sario got fired. Jessica later got fired.

10 THE COURT: Ms. Brancaccio, the question is --

11 THE WITNESS: Sorry.

12 THE COURT: -- you could have called the hotline.

13 THE WITNESS: I could have called the hotline. I  
14 don't trust -- I didn't trust it, as I stated earlier.

15 BY MS. BROWN:

16 Q. That was my only question.

17 A. I'm sorry. I apologize.

18 THE COURT: Sure. I just want you to focus on the  
19 question.

20 THE WITNESS: Sure.

21 THE COURT: And you have redirect. Your counsel is  
22 going to come back up.

23 THE WITNESS: Okay.

24 THE COURT: But when she asks a question, just focus  
25 on the question being asked. Okay?

1 MS. BROWN: And, Your Honor, I move to strike that  
2 answer. That was not responsive.

3 THE COURT: Any objection there?

4 MR. WIRMANI: No, Your Honor.

5 THE COURT: I'll strike the response other than her  
6 response to the call to the hotline.

7 BY MS. BROWN:

8 Q. So my question -- excuse me, Ms. Brancaccio -- was simply  
9 when you got this email and you sort of refreshed yourself on  
10 the email in 2012, you could have called the hotline.

11 True?

12 A. Correct.

13 Q. You did not.

14 Correct?

15 A. Correct.

16 Q. All right.

17 And this wasn't the only way or the only opportunity  
18 that you had while you were at Janssen to report this alleged  
19 misconduct.

20 Correct?

21 A. Correct.

22 Q. And you knew that.

23 Right, ma'am?

24 A. Yes, ma'am.

25 Q. All right.

1 MS. BROWN: Let's look at tabs 16 and 17, please.

2 Your Honor, permission to admit D-2276 and the  
3 attachment, 2277.

4 MR. WIRMANI: No objection, Judge.

5 THE COURT: All right. So admitted.

6 (Defendants' Exhibit D-2276 in evidence.)

7 (Defendants' Exhibit D-2277 in evidence.)

8 BY MS. BROWN:

9 Q. So we're going to take a look. This, again, to orient  
10 us, we're now -- if we look at the top of this email, this is  
11 something else that you forwarded from your Janssen account  
12 where it says this TTT U.S. That's Tibotec. That's your  
13 Janssen account.

14 Right?

15 A. Yes.

16 Q. Okay.

17 So you forward it from your work email to your personal  
18 email about a month before you're ready to sue Janssen.

19 Correct?

20 A. That's correct.

21 Q. Okay.

22 And down below -- and why did you forward this to your  
23 personal account?

24 A. I don't -- I couldn't answer that right now. I don't  
25 know.

1 Q. All right. Well, let's take a look at it. Maybe it will  
2 refresh you.

3 Here's what the email was below that you forwarded from  
4 your work account to your personal account. And it comes from  
5 Catherine Kaucher, the health care compliance officer. You  
6 know her.

7 Right?

8 A. Yes, I do.

9 Q. You know her pretty well.

10 Right, ma'am?

11 A. No, I wouldn't say pretty well. I know her and I know of  
12 her.

13 Q. All right.

14 And what she's talking about is a great POA meeting  
15 that took place a few weeks ago.

16 Right?

17 A. Yep.

18 Q. And those are kind of the big sales meetings that  
19 happened frequently a couple times a year, maybe?

20 A. One to two times, yeah.

21 Q. One to two times.

22 And you attend those like the rest of the sales force.

23 Correct?

24 A. Yes.

25 Q. And you know one of the things that happens at those

1 meetings is compliance training and compliance directives.

2 Correct, ma'am?

3 A. Yes.

4 Q. All right.

5 And sometimes Ms. Kaucher is the one giving those  
6 presentations and taking questions from the audience.

7 Right?

8 A. Yes.

9 Q. And one of the things Ms. Kaucher did is she instituted  
10 something called HCC red bag questions.

11 Do you remember that, ma'am?

12 A. Yes.

13 Q. And what she did actually is physically put a red, like,  
14 gift bag in the back of the room at the POA meeting so people  
15 could write questions and drop them in the bag without anyone  
16 knowing who they were.

17 Right?

18 A. Yes.

19 Q. All right.

20 And so she says, actually, this thing was a huge  
21 success. Right? It was well received.

22 Do you see that?

23 A. That's what she said.

24 Q. And so she says she is going to continue to make it  
25 available at all of the POAs.

1 Do you see that?

2 A. Yes.

3 Q. And she says, "This is an opportunity for you" -- that's  
4 including you, anybody in the field -- "to ask any sort of  
5 compliance questions with the option to remain anonymous."

6 Do you see that?

7 A. I see that.

8 Q. And you knew that you had this option to use the red bag,  
9 and you did not.

10 Correct?

11 A. I did not.

12 Q. All right. Let's look at what some of your colleagues,  
13 though, were concerned about when they did use the red bag.

14 So if we go to the attachment, you know what  
15 Ms. Kaucher does is when she collects all the questions that  
16 are in the red bag, she keeps it anonymous, right, and she  
17 circulates the question and the answer.

18 Correct?

19 A. Yes, she did do that.

20 Q. All right.

21 And this happened more than once. She had this program  
22 running for a number of years.

23 You know that, right?

24 A. I know that she had it running. I couldn't tell you how  
25 many years.

1 Q. All right.

2 And so there's a bunch of questions here that people  
3 asked. "Can medical science liaisons take customers to an  
4 off-site meal?"

5 Do you see that?

6 A. Yes.

7 Q. And some folks were even asking questions about some  
8 things that you raised with our jury, which is the educational  
9 materials that were being provided to the sales force to keep  
10 them updated on developments in the field.

11 Do you remember that?

12 A. I see it here. I didn't recall it before I saw it.

13 Q. So one of your colleagues actually wanted to know "Can we  
14 get more of this scientific information? Can we get more  
15 study-related information on our medicines or our competitor  
16 medicines sent to us as an update more regularly?"

17 One of your colleagues wanted more of that, right?

18 A. I see that.

19 Q. And he or she made it clear: "FYI, I'm not saying we're  
20 going to share it. We just want it for education."

21 Right?

22 A. Yes, I see this.

23 Q. Ms. Kaucher makes clear "Maybe the sales training folks  
24 can get you some educational-use-only stuff, but you can't  
25 discuss it outside of the company."



1 Right?

2 A. Yes.

3 Q. "Only study information that can be discussed are  
4 approved materials and messages."

5 Right, ma'am?

6 A. That's what it says.

7 Q. And some of your folks are -- some of your colleagues at  
8 Janssen were so concerned about not running afoul of  
9 compliance issues that they had a bunch of questions about  
10 snacks.

11 Did you know that?

12 A. No.

13 Q. Some of your folks are so worried about making sure  
14 they're doing the right thing that they had to double-check  
15 about snacks. And there's a bunch of questions, you know, in  
16 this red bag situation where people are very concerned about  
17 snacks.

18 Did you know that?

19 A. I didn't.

20 Q. All right.

21 Well, this folks -- this person wants to know, "If you  
22 give a snack to a doctor, do we need to record that even if  
23 it's, you know, under \$25?"

24 Right?

25 A. I see that.

1 Q. And Ms. Kaucher responds to that. Right? And she says,  
2 "It's not just the person eating the snack. Anybody who gets  
3 a snack, we need a record of it."

4 Right?

5 A. Yes.

6 Q. And then you see right below it we got questions about  
7 sign-in sheets for snacks.

8 Right?

9 A. Yes.

10 Q. Your colleagues are very concerned about making sure,  
11 even for something as small as a snack, making sure they're  
12 being compliant?

13 A. According to this, it seems that way.

14 Q. Yeah.

15 And one of the things that came up that we just looked  
16 at in this red bag stuff had to do with educational studies  
17 being given to the field for their information only.

18 Right?

19 A. Yes.

20 Q. And you talked about that on your direct examination.

21 True?

22 A. I did.

23 Q. And I recall you saying that you didn't get educational  
24 materials for any of the other HIV medicines that you were  
25 promoting.

1 Do you remember that?

2 A. Yes.

3 Q. All right.

4 Let me see if I can refresh you on that, though, ma'am,  
5 because I think you did.

6 MS. BROWN: Tab 59 and the attachment 60. Permission  
7 to admit D-8838 and D-8839.

8 MR. WIRMANI: No objection, Judge.

9 THE COURT: All right. So admitted.

10 (Defendants' Exhibit D-8838 in evidence.)

11 (Defendants' Exhibit D-8839 in evidence.)

12 BY MS. BROWN:

13 Q. So one of the other -- and we talked -- just to reorient  
14 us on the other medicines you were promoting -- we talked a  
15 little bit about how, in addition to Prezista and Intelence,  
16 you also promoted some other HIV medicines.

17 Correct?

18 A. After those, yes.

19 Q. Sure.

20 At the same time, ma'am.

21 Right?

22 A. You'll have to refresh me. I'm sorry.

23 Q. So, for example, in 2012, you were promoting an HIV  
24 medicine called Complera.

25 Do you remember that?

1 A. Yes.

2 Q. And at one point you were also promoting an HIV medicine  
3 called Edurant.

4 Do you remember that?

5 A. Yes.

6 Q. And as I understand your testimony, you promoted Edurant  
7 and Complera on-label but Prezista and Intelence off-label.

8 Right?

9 A. Yes.

10 Q. All right.

11 Even though you had the same managers and you were in  
12 the same district going to the same doctors.

13 A. Yes.

14 Q. All right.

15 And I thought I heard you say, Well, we never got any  
16 of that for-your-education-only stuff for the other HIV  
17 medicines. And I want to take a look at an email you received  
18 on that.

19 Okay, ma'am?

20 A. Sure.

21 Q. All right.

22 So if we start -- and just to orient us, this makes its  
23 way to you because it comes from your manager, Tony Dolisi.

24 Do you see that?

25 A. Yes.

1 Q. All right.

2 And so this is now August of 2012. And at this point  
3 in time, you and Ms. Penelow are getting the complaint ready.

4 Correct?

5 A. Yes, we are.

6 Q. All right.

7 And Mr. Dolisi sends it to you and others in your  
8 district. And what's below is information that's being  
9 provided as a background on an off-label study for an HIV  
10 medicine called Complera.

11 Correct?

12 A. Yes.

13 Q. All right.

14 And it's -- the particular name of the study is Spirit.

15 Do you see that?

16 A. Yes, I do.

17 Q. And like we've seen in the other emails where this  
18 information is being given to the field, they say, If a  
19 physician is requesting information on Spirit, you got to fill  
20 out an MIR process.

21 Correct?

22 A. Yes.

23 Q. And if we look at the information that was being given to  
24 you and others who were promoting Complera at the time -- this  
25 is D-8838 -- 39, I apologize -- it's something called "Medical

1 Information Backgrounder."

2 Correct?

3 A. I see that, yes.

4 Q. And it says right up at the top what we've seen on all  
5 this information-only stuff, which is that "this is for your  
6 background only."

7 Right?

8 A. Yes.

9 Q. "Not to be discussed with or distributed to any health  
10 care professional."

11 Right?

12 A. Correct.

13 Q. "And if a health care professional asks a question, you  
14 got to do the MIR process."

15 Right?

16 A. Yes, I see that.

17 Q. And your testimony to our jury is that, as it relates to  
18 the instructions on the medical information for Complera, you  
19 followed those instructions.

20 Right?

21 A. I did.

22 Q. All right.

23 As it relates to this document that tells you, Don't  
24 show it to a physician, don't promote with it, as it related  
25 to Complera, you did that.

1 Right, ma'am?

2 A. That's correct.

3 Q. But your testimony in this lawsuit is, as it related to  
4 Prezista and Intelence, you ignored this direction?

5 A. I ignored what direction?

6 Q. Well, you got similar background information or studies  
7 on Prezista and Intelence.

8 Right, ma'am?

9 A. Yeah.

10 Q. And as it related to those studies, they also said, This  
11 is for your information only, don't distribute it in the  
12 field.

13 Right, ma'am?

14 A. That's correct.

15 Q. Okay.

16 And as it related to Prezista and Intelence, you  
17 ignored those instructions.

18 True?

19 A. Because verbally we were told something else by district  
20 managers and key account manager.

21 Q. So my question was just: As it related to Prezista and  
22 Intelence, you ignored those instructions.

23 Correct?

24 A. Yes.

25 Q. As it relates to Complera, you followed them.

1 True?

2 A. Correct.

3 Q. When you were getting ready to file your lawsuit, you  
4 also looked at some specific J&J policies that reminded you of  
5 your obligation to report.

6 Do you remember that, ma'am?

7 A. No, I don't.

8 MS. BROWN: Tab 18, permission to admit D-8544.

9 THE COURT: I'm sorry. It's not -- it's not  
10 previously admitted, correct?

11 MS. BROWN: Correct, Your Honor.

12 THE COURT: All right. Counsel, let me know.

13 MR. WIRMANI: No objection, Judge.

14 THE COURT: All right. So admitted.

15 MS. BROWN: Thank you, Your Honor.

16 (Defendants' Exhibit 8544 in evidence.)

17 BY MS. BROWN:

18 Q. Here is another one of the emails you sent from your work  
19 to your Gmail in connection with the lawsuit.

20 Right, ma'am?

21 A. Yes.

22 Q. Okay.

23 And this is January of 2012. So it would have been  
24 almost a year before you filed the lawsuit.

25 Correct?



1 A. Correct.

2 Q. And when -- you titled the subject here "HCC policies."

3 Do you see that?

4 A. Yes.

5 Q. And certainly you were familiar with because you sent a  
6 bunch of them to yourself, J&J policies, that prohibited the  
7 very allegations -- this very conduct you're alleging in this  
8 case.

9 Right, ma'am?

10 A. Yes.

11 Q. And why is it in January of 2012 that you were forwarding  
12 those policies to yourself?

13 A. I couldn't tell you what -- why I did that at that point.

14 Q. Were you reminding yourself that you had an obligation to  
15 report the conduct that you were getting ready to put in a  
16 complaint in a lawsuit for a lot of money?

17 A. Again, I don't remember why I forwarded that to myself.

18 Q. Did --

19 A. It's a long time ago.

20 Q. I apologize.

21 A. It's okay.

22 Q. Did you look at these policies when you sent them to  
23 yourself and Ms. Penelow?

24 A. Again, I can't remember. It's just -- it's a link, so I  
25 don't know -- I don't know why I did it or what I looked at at

1 that point.

2 Q. You did it a bunch of times.

3 Do you know that?

4 A. No.

5 Q. And this policy, ma'am, that you linked to here, it's  
6 already in evidence. Our jury's already seen it, 2095, and  
7 you know --

8 MS. BROWN: Your Honor, permission to display. It's  
9 in evidence.

10 THE COURT: Yes, you may.

11 BY MS. BROWN:

12 Q. Do you know that this is our promotion of FDA-regulated  
13 products, and you know that it contains, like all of the  
14 policies, a section on an employee's responsibility to  
15 disclose the type of conduct you're alleging in this case.

16 Right, ma'am?

17 A. Yes.

18 Q. And it always provides ways in which an employee can do  
19 that, including through a hotline or a website.

20 Correct?

21 A. Yes.

22 Q. And to be clear, at no time during your work at Janssen  
23 did you report the conduct that you're alleging in this case.

24 Correct?

25 A. That's right.

1 Q. You also, ma'am, reminded yourself of training you  
2 received on reporting alleged off-label conduct.

3 Do you recall that?

4 A. No.

5 Q. This is tab 20.

6 MS. BROWN: Your Honor, permission to admit D-2297.

7 MR. WIRMANI: No objection, Judge.

8 THE COURT: So admitted.

9 MS. BROWN: Okay.

10 (Defendants' Exhibit 2297 in evidence.)

11 BY MS. BROWN:

12 Q. Now, Ms. Brancaccio, to orient us, this is another email  
13 you sent from your work account to your personal account.

14 Do you see that?

15 A. Yes.

16 Q. Now, this one is after the lawsuit has already been  
17 filed.

18 Do you see that?

19 A. Yes.

20 Q. All right.

21 So you've already sued Janssen, right, which you did in  
22 December of 2012.

23 True?

24 A. Yes.

25 Q. And here in June of 2013, you're forwarding information

1 to your personal account about a training you were required to  
2 participate in about how to report any alleged misconduct.

3 Correct?

4 A. Yes. It seems that way.

5 Q. Why did you do that?

6 A. Again, I don't know why I forwarded it to myself after  
7 the fact.

8 Q. "And after the fact," you mean after you already sued  
9 Janssen?

10 A. Correct.

11 Q. All right.

12 And if we go down here, we see you were forwarding an  
13 email called -- about required training.

14 Right?

15 A. Yes.

16 Q. And this one, this went from someone at J&J to you at  
17 J&J.

18 Correct?

19 A. Yes.

20 Q. At Janssen, required training off-label use reporting for  
21 field personnel.

22 Right?

23 A. Yes.

24 Q. And this was identified as a mandatory training you had  
25 to participate in.

1 Right, ma'am?

2 A. Yes.

3 Q. And you did participate in it.

4 True?

5 A. Yes.

6 Q. And it told you not only that you were required to  
7 report, but it helped you understand the ways in which you  
8 could report.

9 Correct?

10 A. From reading this, I don't know where it told me to go,  
11 but...

12 Q. There's a little more information on the back about --

13 A. Okay.

14 Q. -- you're being required to do this 30-minute mandatory  
15 training about off-label use reporting for field personnel.

16 Do you see that?

17 A. I do.

18 Q. And that's a training you completed.

19 Right, ma'am?

20 A. I'm sure I did.

21 Q. Okay.

22 And even after completing this training, you did not  
23 report the allegations you're making here.

24 True?

25 A. True.

1 Q. Now, in fact, not only did you not report it, you  
2 continued, according to you, to engage in off-label promotion.

3 Right, ma'am?

4 A. Yes.

5 Q. So even though at this point, now in June of 2013, you  
6 have already sued Janssen.

7 True?

8 A. That's true.

9 Q. You've had lawyers for almost two years now.

10 Right?

11 A. Yes.

12 Q. You are right now engaging with the Government.

13 True?

14 A. Yes.

15 Q. And you are reminded that you have a mandatory training  
16 about how to report this stuff.

17 Right?

18 A. Yes.

19 Q. And you, according to your testimony, nevertheless,  
20 continued to engage in what you've described as illegal  
21 off-label promotion?

22 A. Correct.

23 Q. And you did that, not just at 2012, but 2013 and 2014.

24 Correct?

25 A. Yes.

1 Q. Until you decided to stop.

2 Right?

3 A. Yes.

4 Q. And you had originally told us in your deposition that  
5 you engaged in off-label promotion on every single sales call.

6 Do you remember that?

7 A. Yes.

8 Q. And correct me if I'm wrong, but I thought I heard your  
9 testimony last week that it wasn't actually every single call.

10 Right?

11 A. I said almost every.

12 Q. Okay.

13 It's just most calls now?

14 A. I said almost every.

15 Q. Okay.

16 Sometimes you didn't?

17 A. Sometimes I didn't.

18 Q. All right.

19 Were there particular providers for whom you did not  
20 engage in off-label promotion?

21 A. Yes.

22 Q. Who were they?

23 A. Dr. David Rubin. He was a provider that I did not -- I  
24 did not speak off-label to, but Nancy Bartnett did. There  
25 were just ethical -- some providers that I just didn't go

1 there with.

2 Q. Okay.

3 And it's not -- because sometimes, ma'am, when you  
4 would go -- you would go on a sales call, you didn't have the  
5 chance to see the doctor.

6 Fair enough?

7 A. That's fair.

8 Q. Sometimes you're sort of scheduled to meet with a doctor,  
9 but you get there and you're only able to meet with the staff  
10 or leave something at the office.

11 Correct?

12 A. Yes.

13 Q. It's not every single scheduled call you get time with a  
14 physician.

15 True?

16 A. No. Things happen.

17 Q. And it's certainly not the case that every single  
18 scheduled call you claim you delivered four different  
19 off-label messages.

20 Right?

21 A. That's correct.

22 Q. Meaning you did not do that.

23 Right?

24 A. That's correct.

25 Q. All right.



1 A. I did not.

2 Q. Okay.

3 It would not be fair for someone to assume that every  
4 single time you met with a doctor you provided four different  
5 off-label messages.

6 Correct?

7 A. That would be correct.

8 Q. All right.

9 You received, during your time at Janssen, a number of  
10 trainings and PowerPoints and documents reminding you of your  
11 compliance obligations.

12 Correct, ma'am?

13 A. Yes.

14 Q. All right.

15 MS. BROWN: Tabs 50 and 51, permission to admit  
16 D-8833 and D-8834.

17 MR. WIRMANI: No objection, Judge.

18 THE COURT: All right. So admitted.

19 (Defendants' Exhibits 8833 and 8834 in evidence.)

20 BY MS. BROWN:

21 Q. This is an email, ma'am, from September of 2011, from  
22 Tony Dolisi, your manager, to the New York district, including  
23 you.

24 Right?

25 A. Yes, ma'am.

1 Q. And he's following up on an important topic that was  
2 covered at the POA meeting.

3 Correct?

4 A. Yes.

5 Q. And he says he's attaching dos and don'ts of the  
6 promotional speaker program.

7 Correct?

8 A. Yes.

9 Q. All right.

10 And, in fact, if we just look at the attachment, he  
11 did, in fact, send a fairly thick, maybe 30-page presentation  
12 that was given at the POA meeting about compliance guidelines  
13 for speakers.

14 Right?

15 A. Yes, I see that.

16 Q. And you would have attended that.

17 Right, ma'am?

18 A. More than likely, yes.

19 Q. All right.

20 And what he says here is he's actually going to appoint  
21 an expert in the New York district as the health care  
22 compliance expert.

23 Correct?

24 A. Yes.

25 Q. And that was your colleague, Angel Edwards.

1 Correct?

2 A. Yes.

3 Q. And her role was going to be on each of the conference  
4 calls to review a different health care compliance topic.

5 Correct?

6 A. Yes.

7 Q. And he says the first one you all were going to start  
8 reviewing was "what was discussed at the POA around not  
9 emailing invitations for promotional programs."

10 Do you see that?

11 A. Yes.

12 Q. Okay.

13 There was a compliance rule that, if you had a speaker  
14 invite, you couldn't email it.

15 Correct?

16 A. Yes.

17 Q. It had to be personally delivered to the doctor.

18 Correct?

19 A. Yes.

20 Q. And you -- Ms. Brancaccio, you took that compliance rule  
21 seriously.

22 Right, ma'am?

23 A. Yes.

24 Q. All right.

25 Let's look at tab 56.

1 MS. BROWN: Permission to admit this document, which  
2 is D-4407.

3 MR. WIRMANI: No objection, Judge.

4 THE COURT: All right. So admitted.  
5 (Defendants' Exhibit 4407 in evidence.)

6 BY MS. BROWN:

7 Q. Who is Marvin Siegel, Ms. Brancaccio?

8 A. Marvin Siegel was -- he worked for a specialty pharmacy.

9 Q. Was he one of the points of contact for one of your  
10 doctors?

11 A. He was a point of contact for the pharmacy.

12 Q. All right.

13 And to orient us here, you have an email chain with  
14 Mr. Siegel in November of 2012, this is just a month before  
15 you file your lawsuit.

16 Right, ma'am?

17 A. Yes.

18 Q. All right.

19 And you talk about how you're going to drop off  
20 invitations to the Kaminsky program.

21 Do you see that?

22 A. Yes.

23 Q. That's an email from you to Mr. Siegel about how you want  
24 to stop by and drop off these invitations.

25 Right?

1 A. Yes.

2 Q. And he responds and says, Well, Christine, can you just  
3 email them to me?

4 Do you see that?

5 A. Yes.

6 Q. "Email me if you have it electronically."

7 He says that's going to be easier for him to get that  
8 out.

9 Right?

10 A. I see that.

11 Q. All right.

12 And you say you can't.

13 Right?

14 A. Uh-huh.

15 Q. Because Janssen's tracking you.

16 Right?

17 A. Yes.

18 Q. We're not allowed to do that anymore for compliance  
19 reasons.

20 Right?

21 A. Yes.

22 Q. All right.

23 You had actually just been trained on that compliance  
24 issue in the deck we looked at.

25 Right?

1 A. Yes.

2 Q. And Mr. Dolisi was talking about reviewing that  
3 compliance program with the HCC expert, Angel Edwards.

4 Right?

5 A. Yes.

6 Q. And you took that seriously.

7 Right, ma'am?

8 A. Yes.

9 Q. So you tell Mr. Siegel, I can't do it. It's a compliance  
10 issue, right?

11 A. Yes.

12 Q. And there is a little back and forth about how you're  
13 going to drop it off anyway.

14 And you say, "Okay, I'll do it. It's a health care  
15 compliance policy, and they have been" -- "people have been  
16 nailed emailing it."

17 What do you mean by that?

18 A. They've gotten in trouble for emailing it.

19 Q. Sure. Janssen was monitoring compliance issues like  
20 this, and if people were found to be violating a compliance  
21 policy, they got in trouble for it.

22 Right?

23 A. Yes.

24 Q. And you didn't want to get in trouble for violating a  
25 compliance policy.

1 Right?

2 A. That's right.

3 Q. Because you wanted to be compliant.

4 Correct?

5 A. That's correct.

6 Q. You understood your job promoting an FDA-regulated  
7 medicine is to comply with certain promotional rules and  
8 policies.

9 Correct?

10 A. Yes.

11 Q. And you understood, if you didn't do that, you could be  
12 fired from Janssen.

13 Correct?

14 A. Correct.

15 MS. BROWN: Let's take a look at one more quickly,  
16 Your Honor, permission to admit 61, which is -- actually  
17 Relators' 275.

18 MR. WIRMANI: No objection, Judge.

19 THE COURT: So admitted.

20 (Defendants' Exhibit 61 in evidence.)

21 BY MS. BROWN:

22 Q. And speaking of compliance presentations that you  
23 participated in, this is one of the presentations that was  
24 given at one of the POA meetings.

25 Do you see that, ma'am?

1 A. Yes.

2 Q. Compliance selling and competitive environment, you  
3 underwent this training.

4 True?

5 A. Yes.

6 Q. And one of the things that you were trained on and that  
7 you knew is that the FDA can actually visit speaker programs  
8 and observe and audit and appear at speaker programs.

9 Right, ma'am?

10 A. I know health care compliance. I'm not sure about FDA.

11 Q. All right.

12 And one of the things that you were trained on at these  
13 programs is what you can and can't do in a selling  
14 environment.

15 Correct?

16 A. From the title, yes.

17 Q. Right.

18 And so, for example, what can we do -- some product  
19 attributes are undeniable and don't require head-to-head data.

20 Right?

21 A. Right.

22 Q. There are some comparisons that can be made between  
23 medicines that don't require a randomized controlled clinical  
24 trial.

25 You would agree with that.



1 Right?

2 A. Yes.

3 Q. And we spoke a little bit about that last week. One of  
4 those would be dosing.

5 Correct?

6 A. Yes.

7 Q. And we talked about that in the context of that reporting  
8 you made with Nancy Bartnett.

9 Do you remember that?

10 A. Yes, I do.

11 Q. Because one of the things Ms. Bartnett talked about was a  
12 hundred milligrams of ritonavir with Reyataz, and a hundred  
13 milligrams of ritonavir with Prezista, and you said you didn't  
14 have an issue with that.

15 Right, ma'am?

16 A. No, I don't.

17 MR. WIRMANI: Objection. That mischaracterizes her  
18 testimony, Judge.

19 MS. BROWN: I can rephrase if --

20 THE COURT: Rephrase.

21 All right. Objection sustained.

22 MS. BROWN: Sure.

23 BY MS. BROWN:

24 Q. And there's nothing wrong with that.

25 Right, Ms. Brancaccio?

1 A. No.

2 Q. Right.

3 Because comparing a dosing regime can be done without  
4 head-to-head data.

5 True?

6 A. That's true.

7 Q. All right.

8 When you produced to us the secret recording that you  
9 made in this case, you also produced to us recordings of some  
10 of your compliance training and the compliance programs you  
11 attended.

12 Fair enough, ma'am?

13 A. Yes.

14 Q. All right.

15 And there were several programs where we hear on the  
16 tapes or on your phone Ms. Catherine Kaucher giving compliance  
17 training or compliance speeches.

18 Correct?

19 A. They were in my computer, yes.

20 Q. Right.

21 And the reason they were in your computer is because  
22 you had to complete compliance training -- some of it was done  
23 online.

24 Correct?

25 A. Yes.

1 Q. And one of the recordings you gave us actually involves a  
2 presentation that explains what happened to a Janssen employee  
3 when they reported something out of compliance.

4 Correct?

5 A. I don't recall that recording, so --

6 Q. All right.

7 Let's --

8 A. -- I can't answer that.

9 MS. BROWN: Your Honor, I would seek to admit D-4513,  
10 which was the audio file produced from Ms. Brancaccio at  
11 Janssen RELO68081.

12 MR. WIRMANI: No objection.

13 THE COURT: So admitted. You can play it.

14 MS. BROWN: Could we play D-4513, please, Mr. Knecht.

15 (Audio recording is played at this time.)

16 BY MS. BROWN:

17 Q. And to be clear, Ms. Brancaccio, the medicine that  
18 they're talking about in this recording wasn't Prezista or  
19 Intelence.

20 Correct?

21 A. That's right.

22 Q. They're talking about something called Nuta ER [sic]?

23 A. Nucynta.

24 Q. Nucynta. Thank you.

25 Do you know what kind of medicine that is?

1 A. No, I can't recall it.

2 Q. All right.

3 Not one that you promoted.

4 Right?

5 A. No.

6 Q. But, nevertheless, they described a situation similar to  
7 some of the allegations you've made in this case.

8 Correct?

9 A. Yes.

10 Q. They describe a situation where a speaker spoke outside  
11 of the approved speaker deck.

12 Correct?

13 A. Yes.

14 Q. And they describe a sales district manager who was at the  
15 speaker event.

16 Correct?

17 A. Yes.

18 Q. They described that person taking corrective action.

19 Correct?

20 A. Yes, they did.

21 Q. And they describe -- rather than getting fired or  
22 retaliated, they describe that salesperson getting an award.

23 Correct?

24 A. Yes, that's what it said.

25 Q. All right.

1           You -- even after you filed this lawsuit against us,  
2 Ms. Brancaccio, you continued to look for home-run or  
3 slam-dunk evidence.

4           Correct?

5 A.    I'm not sure what you mean.

6           MS. BROWN: Tab 91. Permission to admit D-8856.

7           MR. WIRMANI: No objection, Judge.

8           THE COURT: So admitted.

9 (Defendants' Exhibit D-8856 in evidence.)

10          MS. BROWN: Can I have the ELMO, please.

11          Thank you.

12 BY MS. BROWN:

13 Q.    And first of all, just so we understand how we're able to  
14 see this email, if we look at the very top -- and I apologize.  
15 It will hopefully come into focus -- there we go.

16          You forwarded this email to your boyfriend at the time.

17          Is that right, ma'am?

18 A.    Yes.

19 Q.    And so our jury understands, normally when you're talking  
20 to your lawyers, that -- that should be privilege, right? We  
21 don't get to see that.

22          Correct?

23 A.    Yes.

24 Q.    But we have looked at that email last week about the  
25 lawyers suggesting the kickback claims, and we got to see that

1 because Ms. Penelow forwarded it to her mom.

2 Do you remember?

3 MR. WIRMANI: Objection. Mischaracterizes the  
4 documents.

5 THE COURT: Overruled. You can clean it up on  
6 redirect.

7 BY MS. BROWN:

8 Q. We got to see that document because it had been forwarded  
9 to somebody who wasn't a lawyer.

10 Correct?

11 A. Yes.

12 Q. All right.

13 And this email, too, even though we're going to look at  
14 some stuff between you and your lawyers, we're getting to look  
15 at that because you forwarded it to your boyfriend.

16 Correct?

17 A. Yes.

18 Q. All right.

19 And so if we look down at the bottom, this email starts  
20 out -- let me see if we have the first one.

21 Okay. So the first one actually in the chain is you,  
22 again, forwarding a document from your work account at Janssen  
23 to your Gmail account.

24 Correct?

25 A. Yes.

1 Q. And at this point in 2014, you -- your lawsuit had  
2 already been on file for, like, a year and a half.

3 Correct?

4 A. Yes.

5 Q. Okay.

6 And you forwarded it to yourself, this deck, and then  
7 you send an email to your lawyers describing what you're  
8 forwarding.

9 Okay?

10 A. Yes.

11 Q. Do you see that?

12 A. Uh-huh.

13 Q. And you say to your lawyers, "Please see the attached  
14 slide deck from the speaker program I had last night."

15 Do you see that?

16 A. Yes.

17 Q. And first of all, sales reps aren't supposed to take the  
18 speaker deck with them.

19 Correct?

20 A. No.

21 Q. Right.

22 The third party, particularly by 2014, the third-party  
23 vendor that operates the speaker program, they're the ones  
24 that are supposed to have control of the speaker decks.

25 Correct, ma'am?

1 A. I don't entirely think that's true, no.

2 Q. Okay.

3 Do you understand that's the policy, ma'am?

4 A. No. I really don't.

5 Q. Okay.

6 In any event, you weren't supposed to take this speaker  
7 deck.

8 True?

9 A. True.

10 Q. All right.

11 But you did it because still here, you're working on  
12 providing the lawyers with evidence for your lawsuit.

13 Right?

14 A. Yes.

15 Q. Even after we had already been sued.

16 Right?

17 A. Yes.

18 Q. All right.

19 And you say, "Slides 11 and 20 are very important."

20 Right?

21 A. Yes.

22 Q. You point out that you believe slide 11 supports what the  
23 Government was asking us for at their last request.

24 Right?

25 A. Yes.



1 Q. And then you say, "Slide 20 is," all caps, "binding  
2 affinity."

3 Do you see that?

4 A. Yes.

5 Q. Two exclamation points.

6 Right?

7 A. Yes.

8 Q. And that's because you used to have claims that you  
9 believed sales reps were promoting something called binding  
10 affinity off-label.

11 Right, ma'am?

12 A. That's right.

13 Q. The reason you were excited, all caps, two exclamation  
14 points, is because you used to complain about some different  
15 off-label messages.

16 True?

17 MR. WIRMANI: Your Honor, I object.

18 Can I approach?

19 THE COURT: You may.

20 (Sidebar begins at 10:56 a.m.)

21 THE COURT: Yes.

22 MR. WIRMANI: There's a motion in limine that was  
23 granted on the amended complaint. She keeps talking about  
24 what she had complained about versus what she's complaining  
25 about now, which is clearly a reference to the amended

1 complaint.

2 MS. BROWN: I'm very aware of that motion in limine.  
3 I'm not running afoul of it, Your Honor. I'm using this  
4 document to talk about the fact that she used to have  
5 different complaints. And, in fact, there are other documents  
6 that show when they were meeting with the Government they were  
7 talking all about binding affinity that everybody just walked  
8 away from now.

9 THE COURT: And you believe that goes too close to  
10 raising the amended complaint -- you haven't raised the actual  
11 complaint in the case, have you?

12 MS. BROWN: And I'm not going to, correct. Correct.  
13 Correct, Your Honor.

14 THE COURT: What are your thoughts about that? She  
15 hasn't raised anything -- when she's saying "complaint," I  
16 don't think she's using the formal final complaint in the  
17 lawsuit. You said -- you've been complaining that this was a  
18 problem in the beginning, and now you're complaining something  
19 else is a problem, which goes potentially to credibility.  
20 Right? That's what she's attacking.

21 MR. WIRMANI: I think it's awfully close to the line.

22 THE COURT: I think it is too, but I don't think it's  
23 that close. So here is what I'm going to say.

24 I'm going to overrule the objection for now, but,  
25 Ms. Brown, since we've had this discussion, you know not to go

1 any closer than what you've been doing.

2 MS. BROWN: Promise.

3 THE COURT: Fair enough?

4 MS. BROWN: Yes.

5 THE COURT: Okay.

6 MS. BROWN: Thanks, Judge.

7 (Sidebar was concluded at 10:58 a.m.)

8 (Open court.)

9 MS. BROWN: May I proceed, Your Honor?

10 THE COURT: You may.

11 BY MS. BROWN:

12 Q. We were talking about this binding affinity, exclamation  
13 points, and that's because you used to believe there were  
14 problems with the binding affinity message that sales reps  
15 were given.

16 Correct?

17 A. Yes.

18 Q. All right.

19 And you understand now -- now you don't -- now you  
20 think that's okay? You're not raising those in this lawsuit.

21 Right?

22 A. I still don't think it's okay, but it's not part of the  
23 claim.

24 Q. Okay.

25 And what you say as it relates to this deck, that

1 binding affinity stuff, is that "We find it very interesting  
2 that Nancy Bartnett recently went in-house as the national  
3 trainer for HIV and this slide is now in a speaker deck."

4 Do you see that?

5 A. Yes.

6 Q. What are you talking about?

7 A. Well, she went in as national sales trainer for the  
8 entire country, and now the -- now we're talking about -- the  
9 speakers are talking about binding affinity in the deck that  
10 they have to speak with.

11 Q. Okay.

12 What does that have to do with Nancy Bartnett?

13 A. That she went -- now that she -- she trained us out in  
14 the field, and now she's in-house training nationally the new  
15 reps that are coming in.

16 Q. All right.

17 And you believed there was a problem with the binding  
18 affinity message.

19 Correct?

20 A. Yes.

21 Q. All right.

22 And that's no longer a problem you're raising in this  
23 lawsuit.

24 True?

25 A. It's no longer -- it's no longer one of the claims, no.

1 Q. Okay.

2 And then you say here at the end, "Home run," question  
3 mark, question mark, question mark.

4 Do you see that?

5 A. Yes.

6 Q. You thought that this speaker deck that you weren't  
7 supposed to take, but you did and gave to your lawyers, was a  
8 home run for your lawsuit, ma'am?

9 A. Well, because we claimed -- we had the claim initially  
10 about binding affinity and how we, as reps -- and we were  
11 going around talking about --

12 THE COURT: Sorry. Counsel, let me see counsel for a  
13 moment.

14 Sorry, ma'am. I need to talk to counsel.

15 (Sidebar begins at 11:00 a.m.)

16 THE COURT: So this is where I get upset. Right?  
17 Because now you have the witness testifying that she had a  
18 part in the initial complaint.

19 MS. BROWN: I don't think she said "complaint" at  
20 all, Your Honor. She said "claim."

21 THE COURT: We initially had a claim.

22 MS. BROWN: Claim, yeah.

23 THE COURT: That's about this case. That's about a  
24 complaint, Ms. Brown, whether she said "complaint" or not. So  
25 that's where you couldn't go. Right?

1           So I'm going to strike the question and the response.  
2           You made your point --

3           MS. BROWN: Okay. I'll reask the home run question  
4           about her concern. Can I use the word "concern"?

5           THE COURT: Yeah. I just don't want to get into  
6           claims or complaint. I understand that you didn't say it in  
7           your question, but that's the danger of getting this close.

8           MS. BROWN: I understand. I understand.

9           I'll just say, You thought this was a home run for your  
10          concerns.

11          THE COURT: For your concerns.

12          MS. BROWN: Is that fine?

13          THE COURT: That's fair. And just say "yes" or "no."  
14          I don't want her to say "complaint," "claim."

15          MS. BROWN: Yeah, okay.

16          (Sidebar was concluded at 11:01 a.m.)

17          (Open court.)

18          THE COURT: Folks, I'm just striking the last  
19          question and response to the extent -- it was a partial  
20          response anyway, but don't consider the question or the  
21          partial response for purposes of your deliberations.

22          BY MS. BROWN:

23          Q. And, Ms. Brancaccio, just "yes" or "no," ma'am. You  
24          considered this information you were passing along in this  
25          email to be a home run for your concerns.

1 Right?

2 A. Yes.

3 Q. All right.

4 Now --

5 THE COURT: I'm sorry, Ms. Brown. Let me know -- I  
6 want to give the jurors a short break, but I don't know if  
7 you're switching topics or if you want me to wait a few  
8 minutes.

9 MS. BROWN: I am, Your Honor, and I'm nearing the  
10 end, so this is a perfect time.

11 THE COURT: All right. Folks, let's take a  
12 ten-minute break, and then we'll continue with witnesses.

13 Let's get the jury excused.

14 THE DEPUTY COURT CLERK: All rise.

15 (Jury excused.)

16 THE COURT: All right, folks. Have a seat.

17 Ms. Brancaccio, you're on break, too, so you can come  
18 off of the witness stand.

19 Just a quick thing on the trial schedule. We're  
20 already changing it. At the lunch break, I want to see  
21 counsel in chambers. I'm going to have to tweak the --  
22 already, just looking at what's coming up during  
23 deliberations, when we anticipate the jury is going to get it,  
24 I'm going to tighten up the schedule a little bit more.

25 And just to be clear, I have added the half day back on

1 May 23rd. I'm also adding June 5th back in, but I'm taking  
2 off the 12th. So I'm letting you all know that. But because  
3 of that, I'm still going to tighten your schedule a little  
4 more than I said earlier this morning.

5 So at lunch, let me see all of you so we can make sure  
6 that we can get this case to the jury at the appropriate time.

7 The reason why I say that is we have no judges on the  
8 court on the 18th and the 19th is a holiday. So this case has  
9 to go to this jury before June 17th. So I'm going to talk to  
10 you about those tweaks over the lunch break.

11 With that, please be seated. You're on recess.

12 (A short recess occurred.)

13 THE DEPUTY COURT CLERK: Please remain seated.

14 All rise.

15 (Jury enters the courtroom.)

16 THE COURT: Everybody be seated.

17 Ms. Brown, you may proceed.

18 MS. BROWN: Thank you, Your Honor.

19 BY MS. BROWN:

20 Q. Ms. Brancaccio, when we left off, we had looked at an  
21 email where you specifically identified Nancy Bartnett.

22 Do you recall that?

23 A. Yes.

24 Q. And, actually, a number of the allegations you made with  
25 our jury last week and in your complaint and in your



1 deposition have to do with Nancy Bartnett.

2 Don't they, ma'am?

3 A. Yes.

4 Q. And the fact of the matter is you don't like Nancy  
5 Bartnett that much, do you, ma'am?

6 A. That's not true.

7 Q. Okay.

8 Well, you and Ms. Penelow actually have exchanged a  
9 number of emails about Ms. Bartnett that aren't that nice.

10 Right, ma'am?

11 A. I don't recall that.

12 MS. BROWN: Let's take a look at tab 72, please.

13 Your Honor, permission to admit D-8510.

14 MR. WIRMANI: No objection, Judge.

15 THE COURT: So admitted.

16 (Defendants' Exhibit D-8510 in evidence.)

17 BY MS. BROWN:

18 Q. And, Ms. Brancaccio, this is an email that starts --  
19 actually, we start on the back page. It starts with an email  
20 from Tim Mcsherry to folks in the New York region.

21 Do you see that?

22 A. Yes.

23 Q. And Tim Mcsherry, he was one of your fellow sales  
24 representatives.

25 Correct?

1 A. Yes.

2 Q. And he's sending an email to you, his colleague, about a  
3 conference call follow-up, "Hi, Kaletra, selective targeting."

4 Correct --

5 A. Yes.

6 Q. -- And then Nancy Bartnett responds and thanks  
7 Tim Mcsherry for putting together this list that he had  
8 circulated.

9 Correct?

10 A. Yes.

11 Q. And then she gives a few points of consideration when  
12 targeting Kaletra providers.

13 Right?

14 A. Yes, I see that.

15 Q. And this email is taking place in August of 2011. She  
16 was a key account manager at this time.

17 Is that right, ma'am?

18 A. Yes.

19 Q. And Ms. Penelow forwards it to you, forwards  
20 Ms. Bartnett's email to you and says, "I'm laughing under my  
21 breath."

22 Do you see that?

23 A. I do.

24 Q. And then you said, "I just read it. Truly unbelievable.  
25 I'm shaking my head."

1 Do you see that?

2 A. Yes, I do.

3 Q. It looks like a pretty standard email, no?

4 A. I would have to really read the entire email --

5 Q. Uh-huh.

6 A. -- to answer that.

7 Q. Do you know why you would be shaking your head about

8 Nancy Bartnett's email?

9 A. No. Again, I have to read it.

10 Q. Let's look at another one, 73, please.

11 MS. BROWN: D-8866.

12 MR. WIRMANI: No objection, Judge.

13 THE COURT: So admitted.

14 (Defendants' Exhibit 8866 in evidence.)

15 BY MS. BROWN:

16 Q. This is another email that starts out with an email from

17 Nancy Bartnett to Tony Dolisi.

18 Do you see that?

19 A. Yes.

20 Q. And Nancy Bartnett is talking about following up on

21 Bill Whyte's question. Who is Bill Whyte?

22 A. He was -- maybe the president or vice president at one  
23 point. I really don't recall his title.

24 Q. All right.

25 Well, Ms. Bartnett sends this story to Mr. Dolisi and

1 then forwards it to Ms. Penelow and a couple of other sales  
2 representatives in Manhattan.

3 Do you see that?

4 A. Yes.

5 Q. And she says, "I thought I'd send this out so you can  
6 take a look at my goal and strategy per Bill Whyte's request."

7 Do you see that?

8 A. Yes.

9 Q. And Ms. Penelow forwards it to you.

10 Right?

11 A. Yes.

12 Q. And she says, "I don't recall Bill saying to stay at home  
13 and write War and Peace about the story of War and Peace  
14 that's already been written. LOL."

15 Right?

16 A. Yes.

17 Q. And let's look at tab 74.

18 MR. WIRMANI: No objection.

19 THE COURT: So admitted.

20 (Defendants' Exhibit 6037 in evidence.)

21 BY MS. BROWN:

22 Q. This email --

23 MS. BROWN: And for the record, Your Honor, 74 is  
24 D-6037.

25 BY MS. BROWN:

1 Q. This email actually starts -- this is April 16th, 2013.

2 Now, you have already sued Janssen.

3 Correct?

4 A. Yes.

5 Q. You've made serious allegations about Ms. Bartnett in  
6 your complaint.

7 Correct?

8 A. That's correct.

9 Q. And you send an email thanking her.

10 Correct?

11 A. Yes.

12 Q. Thanking her for getting you reacquainted with Elmhurst  
13 Hospital in Queens.

14 Correct?

15 A. Yes.

16 Q. And she responds saying it was her pleasure.

17 Right?

18 A. Yes.

19 Q. Nice response from Ms. Bartnett.

20 Right?

21 A. Yes.

22 Q. "Your thanks isn't necessary but very much appreciated."

23 Right?

24 A. Yes.

25 Q. All right.

1 And she says, "As always, please feel free to contact  
2 me."

3 Correct?

4 A. That's right.

5 Q. And you forward this email to your Gmail.

6 Right?

7 A. Uh-huh. Yes.

8 Q. Why did you do that?

9 A. I-- again, I have no idea.

10 Q. And then you forward it to Ms. Penelow.

11 Do you see that?

12 A. Yes.

13 Q. And you say, "Her response below."

14 Do you see that?

15 A. Yes.

16 Q. Why were -- why were you telling Ms. Penelow about what  
17 she had said when you thanked her?

18 A. Again, this was so long ago, I -- there's no context for  
19 me here. I don't -- I don't know why I did it.

20 Q. And you recall Ms. Bartnett had said, "Let me know if  
21 there's anything I can do to help."

22 Right?

23 A. Sure.

24 Q. Ms. Penelow says, "Oh, there's plenty, lady, LOL."

25 Right?

1 A. Yes.

2 Q. And we already looked, ma'am, at an email that's already  
3 in evidence where it looked like you had been greeted -- this  
4 is already in evidence, D-6043.

5 It looks like you had been somehow using  
6 Nancy Bartnett's account to access some speaker data.

7 Do you see that?

8 A. Yes.

9 Q. Do you remember talking about that last week?

10 A. Yes.

11 Q. And just to be clear, that wasn't the only time that you  
12 had emails that started "Welcome, Nancy Bartnett."

13 Correct?

14 A. I just remember this one from last week.

15 Q. Okay.

16 MS. BROWN: I would seek to admit tab 84, 85 and 86,  
17 which is D-8881, D-6044 and D-6046.

18 MR. WIRMANI: No objection.

19 THE COURT: So admitted.

20 (Defendants' Exhibit 8881 in evidence.)

21 (Defendants' Exhibit 6044 in evidence.)

22 (Defendants' Exhibit 6046 in evidence.)

23 BY MS. BROWN:

24 Q. This email that we already admitted last week took place  
25 on October 1st, 2013.

1 Right, ma'am?

2 A. Yes.

3 Q. But there were many more that you were collecting for the  
4 lawsuit.

5 Correct?

6 A. Yes.

7 Q. Okay.

8 Here's another one, D-8881, from a different time on  
9 October 2nd.

10 Correct?

11 A. Yes.

12 Q. This too welcomes you as Nancy Bartnett.

13 Right?

14 A. Yes.

15 Q. Another one here, October 1st, 8:53 p.m., more data you  
16 were collecting from the lawsuit being welcomed as  
17 Nancy Bartnett.

18 Right?

19 A. Yes.

20 Q. Okay.

21 And these are -- the data you were collecting is about  
22 speakers that you included allegations about in your  
23 complaint.

24 Correct, ma'am?

25 A. That is one of the speakers, yes.



1 Q. Uh-huh.

2 And then finally, if we look at this one, another time  
3 on October 1st, you collected additional data about doctors  
4 that you have allegations about in your lawsuit.

5 Correct?

6 A. Yes.

7 Q. Okay.

8 And we started out by looking at an employee spotlight  
9 that you had done at Janssen.

10 Do you remember that?

11 A. Yes, ma'am.

12 Q. And you know that Ms. Bartnett, she was selected for the  
13 employee spotlight, too.

14 Correct?

15 A. I don't know. I'd have to see it.

16 Q. All right.

17 MS. BROWN: Permission to admit D-8882, tab 87.

18 Your Honor, permission to admit D-8882.

19 MR. WIRMANI: No objection.

20 THE COURT: So admitted.

21 (Defendants' Exhibit 8882 in evidence.)

22 BY MS. BROWN:

23 Q. This is an email that starts out with Ms. Bartnett. This  
24 is a picture of Ms. Bartnett.

25 Do you see that?

1 A. Yes.

2 Q. All right.

3 And it starts out with her employee spotlight.

4 Do you see that?

5 A. Yes.

6 Q. Okay.

7 And, actually, if we look at the first page of the  
8 email, we see "October employee spotlight, Nancy Bartnett,"  
9 and the date is October 2011.

10 Do you see that?

11 A. Yes.

12 Q. And you forwarded that to Ms. Penelow.

13 Correct?

14 A. Yes.

15 Q. And you said, "For your entertainment."

16 A. Okay.

17 Q. So what was entertaining about Ms. Bartnett winning the  
18 employee spotlight email?

19 A. I don't know. I would have to read it.

20 Q. Okay.

21 And then another thing that happened as it relates to  
22 Ms. Bartnett quite recently is you used your access at Johnson  
23 & Johnson to try and get personal information about her  
24 employment.

25 Correct, ma'am?

1 A. Yes.

2 Q. Okay.

3 And recently -- by recently I mean 2022, 2023, 2024.

4 Correct?

5 A. Yes.

6 Q. At that point in time, you weren't working with

7 Ms. Bartnett at all.

8 Correct?

9 A. That's correct.

10 Q. At that point in time, your complaint had been unsealed

11 for seven or eight years.

12 Correct?

13 A. Yes.

14 Q. We were headed towards a trial.

15 Correct?

16 A. Yes.

17 Q. And what you were doing, though, was accessing parts of

18 J&J's system to try and get personal information about

19 Ms. Bartnett.

20 Right?

21 A. Dates of employment. That was all.

22 Q. Sure.

23 But you didn't work with her anymore by the time you

24 tried to access this information.

25 A. No, I did not.

1 Q. Right?

2 You were looking at internal J&J's system that gave  
3 personal employee information.

4 True?

5 A. Yes.

6 Q. All right.

7 Including people's cell phone numbers.

8 Right?

9 A. Yes.

10 Q. Including people's home addresses.

11 Right?

12 A. Yes.

13 Q. Including people's start date at the company.

14 Correct?

15 A. Yes.

16 Q. Including people's end date at the company?

17 A. Yes.

18 Q. That's not data that you used for your job promoting  
19 cancer medicines.

20 Correct?

21 A. No.

22 Q. Right.

23 That's data you accessed for purposes of your lawsuit.

24 True?

25 A. Yes.

1 Q. All right.

2 And the printed copy is a little grainy, but let's just  
3 see if we can pull it up, and I'll give counsel a copy first.  
4 I want to look at what you accessed.

5 MS. BROWN: Your Honor, permission to admit D-8869.

6 MR. MARKETOS: No objection, Judge.

7 THE COURT: So admitted.

8 (Defendants' Exhibit 8869 in evidence.)

9 MS. BROWN: Would you mind pulling that up,  
10 Mr. Knecht? Thank you.

11 BY MS. BROWN:

12 Q. Okay.

13 So if we look up at the top, just to get -- to orient  
14 ourselves to the date, we see that this is coming from your  
15 work email at Janssen.

16 Correct?

17 A. Yes.

18 Q. And at this point, you had been, per your request, moved  
19 out of HIV to a different department.

20 Right?

21 A. Yes.

22 Q. And you wanted to do that to get a fresh start. We  
23 talked about that last week.

24 Right?

25 A. Yes, we did.

1 Q. And Janssen said, Okay, and you were given a position  
2 promoting cancer medicines.

3 Correct?

4 A. Yes.

5 Q. All right.

6 And so at this point in time, you have nothing workwise  
7 to do with Ms. Bartnett.

8 True?

9 A. True.

10 Q. And what you do is you take a screenshot and email it  
11 from your work account to your Gmail account.

12 Correct?

13 A. Yes.

14 Q. And that was not long ago, about a year ago, in September  
15 of 2024.

16 Right?

17 A. 2023, yes.

18 Q. I apologize. 2023.

19 And now, why is it that you took a screenshot of this  
20 internal employee information page?

21 A. I think I wanted to find out if she was still with the  
22 company and what department she was in.

23 Q. Okay.

24 And it's a little hard to see on this screenshot, but  
25 you know that it contains the personal information that we

1 just discussed.

2 Correct?

3 A. Yes.

4 Q. Okay.

5 And let's just look at -- that wasn't the only time  
6 after you had ceased working with Ms. Bartnett that you tried  
7 to get personal information about her employment status with  
8 Janssen.

9 Correct?

10 A. Again, you'd have to -- I'd have to see it.

11 Q. Okay.

12 MS. BROWN: Your Honor, I would seek to admit D-8868.

13 THE COURT: Sorry. Is that personal information  
14 going to be redacted?

15 MS. BROWN: Yes, Your Honor. You actually can't see  
16 it.

17 THE COURT: I know I can't see it on the screen.

18 MS. BROWN: Yeah, yeah.

19 THE COURT: But I don't know if that's my eyes or  
20 something else is going on.

21 MS. BROWN: Yeah, yes. It's impossible -- it's  
22 redacted for us.

23 THE COURT: Okay. I was about to grab my glasses.  
24 All right. Understood.

25 MS. BROWN: Thank you.

1 MR. WIRMANI: I don't have any objection, Your Honor,  
2 but I can see telephone numbers and stuff on this.

3 MS. BROWN: It's just the business number that I'll  
4 show so that we make sure we don't see that.

5 THE COURT: It's the business or the personal?

6 MR. WIRMANI: It's hard for me to tell, Judge. I  
7 have no objection.

8 THE COURT: As long as when any documents are going  
9 back to the jury that we're not looking at things that we  
10 don't need, are irrelevant.

11 MS. BROWN: I understand, Your Honor, and I'll make  
12 that clear.

13 THE COURT: Yep.

14 MS. BROWN: I'll make that clear when I put it up.

15 THE COURT: Yep, all right.

16 MS. BROWN: And I'll do it on the ELMO so we can make  
17 sure we don't have any issue with that.

18 BY MS. BROWN:

19 Q. So let me show you another document, and this is now in  
20 2024.

21 Do you see that, ma'am?

22 A. Yes.

23 Q. Okay. Okay.

24 And the subject is "NB." That's Nancy Bartnett.

25 Right?



1 A. Yes.

2 Q. And what is the difference between the other internal  
3 databases you accessed that we just looked at and this JEDS  
4 database that you accessed here?

5 A. I don't know that there was much difference. I -- I was  
6 looking to see when she started when -- when I met her, and  
7 those were -- there's dates on there, I think, start and stop.

8 Q. And we won't show it, but, of course, this is personal  
9 employee information.

10 Right?

11 A. Yes. We have access to it.

12 Q. Right.

13 But you had no business reason to access that, right?

14 A. No.

15 Q. And you understood, at the time you were doing this, that  
16 Nancy Bartnett was a Janssen employee.

17 Correct?

18 A. In January of this year, no, I wasn't sure --

19 Q. Okay.

20 A. -- because the HIV division had been shut down in the  
21 fall of 2023.

22 Q. You understood that, when Nancy Bartnett was working at  
23 Janssen, she was represented by lawyers.

24 Right?

25 A. Yes.

1 Q. Okay.

2 And if you had any questions about Nancy Bartnett,  
3 there was a way you could ask those.

4 Right?

5 A. No, I -- I'm not aware of that.

6 Q. In any event, what you did is access this JEDS system,  
7 and we can agree it has personal information about an  
8 employee.

9 Correct?

10 A. Yes.

11 Q. Okay.

12 Now, as it relates to Nancy Bartnett, you claim in this  
13 lawsuit that it was, in fact, Nancy Bartnett and Mr. Dolisi  
14 who told you to forge MIRs.

15 Correct?

16 A. Yes.

17 Q. And that's a little confusing only because you also claim  
18 that Nancy Bartnett told you not to request MIRs but to send  
19 the requests to her personally.

20 Right?

21 A. Yes.

22 Q. So on the one hand you say she instructs a forged MIR  
23 and, on the other hand, you say, No, no, she said don't do  
24 MIRs at all.

25 Right?

1 A. Right. There were different time periods.

2 Q. Okay.

3 And what you alleged in the complaint but what is  
4 actually not true is that you say Nancy Bartnett pretended to  
5 be a scientific liaison.

6 Right?

7 A. She did not -- she did not pretend to be a scientific  
8 liaison. She was a key account manager, and she would go in  
9 and answer as the scientific liaison.

10 Q. Okay.

11 And one of the things you talked about on your direct  
12 testimony is that is something about the medical liaison named  
13 Mr. Ray Pecini.

14 Do you remember that?

15 A. Yes.

16 Q. And your testimony to our jury is that he was a very  
17 ethical guy.

18 Correct?

19 A. Yes.

20 Q. He did everything right by the book.

21 Correct?

22 A. Yes.

23 Q. So if he was asked to come in and speak to a doctor, he  
24 did that properly and appropriately, and you have no issues  
25 with that.

1 Correct?

2 A. Correct.

3 Q. What you claim is that Ms. Bartnett didn't like that.

4 Right?

5 A. Yes.

6 Q. And so what you told our jurors last week is that she  
7 would tell you not to invite Mr. Pecini but to invite her  
8 instead.

9 Correct?

10 A. Yes.

11 Q. She would go out of her way to make sure Mr. Pecini  
12 didn't get in front of a doctor.

13 Correct?

14 A. Correct.

15 Q. But you knew, Ms. Brancaccio, because you reviewed it  
16 before you came in here, that the only secret recording you  
17 have of a doctor is Ms. Bartnett offering to bring Mr. Pecini  
18 in to talk to the doctor?

19 A. Which physician?

20 Q. Well, you only have one on tape.

21 Right, ma'am?

22 A. Yes.

23 Q. Dr. Turrett?

24 A. Dr. Turrett, yeah.

25 Q. Okay.

1 Dr. Turrett -- we heard from him last week, right? --  
2 is the only evidence you have in this case of what a doctor  
3 says at a sales visit.

4 Right?

5 A. Yes.

6 Q. And you know at that visit Ms. Bartnett said, "Let me  
7 bring in Mr. Pecini."

8 Right?

9 A. I don't -- I don't recall where in that conversation it  
10 was, but...

11 Q. Let's take a listen to it.

12 MS. BROWN: It's already in evidence, Your Honor.  
13 Permission to play it.

14 THE COURT: Yes.

15 MS. BROWN: May we please play clip 6.

16 (Audio clip is played at this time.)

17 BY MS. BROWN:

18 Q. Ma'am, the only recording you have from a doctor's office  
19 shows Ms. Bartnett, in fact, offering to introduce Mr. Pecini  
20 to Dr. Turrett.

21 Correct?

22 A. Yes.

23 Q. You said you participated -- last week you said you  
24 participated in journal clubs, and that's where all this  
25 off-label -- these off-label studies were disseminated.

1 Right, ma'am?

2 A. Yes.

3 Q. And you know that your district, under Anthony Dolisi,  
4 actually didn't have journal clubs.

5 Right, ma'am?

6 A. We discussed -- we discussed a variety of topics on a  
7 district call.

8 MS. BROWN: Permission to admit tab 101, D-8885.

9 MR. WIRMANI: No objection, Judge.

10 THE COURT: So admitted.

11 (Defendants' Exhibit 8885 in evidence.)

12 BY MS. BROWN:

13 Q. This is an email that comes from Anthony Fernandez, which  
14 is talking about journal club discussions and how it's  
15 important to keep them compliant with the HCC guidelines.

16 Do you see that, ma'am?

17 A. Yes.

18 Q. And it gets forwarded to you and your team by  
19 Tony Dolisi, who was your manager at the time.

20 Correct, ma'am?

21 A. Yes.

22 Q. And he forwards it and says, "Well, it doesn't apply to  
23 us because we don't have journal clubs."

24 Right, ma'am?

25 A. That's what it says.

1 Q. Last week you testified that, when you used off-label  
2 messages in the field, your numbers would go up.

3 Do you remember that testimony?

4 A. Yes.

5 Q. And you testified that you kept personal notes that would  
6 allow you to see how a particular message increased a  
7 physician's prescriptions.

8 Do you recall that?

9 A. Yes.

10 Q. Where, ma'am, are those notes?

11 A. They were just personal notes that I scribbled that this  
12 month I was using this study. And I discarded it as time --  
13 you know, over time. I -- I used it, I kept the note for  
14 myself on my desk. When I was done with it, I just threw it  
15 out.

16 Q. Okay.

17 Ma'am, you threw away and destroyed the notes that you  
18 testified to our jury about?

19 A. I threw away notes to myself that I had during the course  
20 of this time period. As I went along, I just -- they were on,  
21 like, scrap pieces of paper.

22 Q. Do you remember testifying to our jury about those notes?

23 A. Yeah.

24 Q. Okay.

25 Do you remember you said, I have notes where I could

1 see what the message was and then how much the prescription  
2 changed.

3 Do you remember that?

4 A. Yes.

5 Q. And you know one of the things that happened in this case  
6 is we asked you could we have your notes.

7 A. And you -

8 Q. Do you remember?

9 A. Yes.

10 Q. Okay.

11 And you said, Sure. And you gave us a couple of  
12 calendar entries.

13 Correct?

14 A. Yes. I gave you what I had.

15 Q. And then we said, Ms. Brancaccio, do you have any other  
16 notes? And do you remember you said no?

17 A. Correct.

18 Q. And then on direct examination, you described notes that  
19 had been destroyed.

20 Correct?

21 A. Yes.

22 Q. You don't have those notes so our jurors can see if they  
23 check out with your testimony.

24 Right?

25 A. No. It was a long time ago.



1 Q. Last week we talked, Ms. Brancaccio, about your  
2 employment at Janssen a little bit at the start of your  
3 examination.

4 Do you remember that?

5 A. Yes, ma'am.

6 Q. You began working with us in 2003.

7 Correct?

8 A. Correct.

9 Q. You are still employed by Janssen today.

10 Correct, ma'am?

11 A. That's still to be determined, yeah.

12 Q. For the time period that you've been sitting with  
13 Ms. Penelow watching the trial, you've been paid by Janssen.

14 Correct, ma'am?

15 A. Yes.

16 Q. You're getting paid this morning while you're testifying  
17 against us.

18 Correct?

19 A. Yes.

20 Q. You told us about a recent president's cup win that you  
21 had in 2022.

22 Do you remember that?

23 A. Yes.

24 Q. That was based on good sales performance that you had  
25 promoting cancer medicines that we make.

1 Correct?

2 A. Yes.

3 Q. And you actually got to go on a trip as a result of that.

4 Is that right?

5 A. That's right.

6 Q. All right.

7 But you know that -- and to be clear, you never  
8 promoted those cancer medicines off-label, according to you.

9 Right, ma'am?

10 A. I did not.

11 Q. So you had good sales performance, so much so that you  
12 won a president's cup with no off-label promotion.

13 Right?

14 A. That's right.

15 Q. All right.

16 But you know that at Janssen, your performance  
17 evaluation is based on more than just sales numbers.

18 Correct?

19 A. Yes.

20 Q. There are other components to the evaluation of a sales  
21 rep that go beyond whether you're selling a lot of medicine.

22 Correct?

23 A. Yes.

24 Q. And some of those things include things like your  
25 communication skills.

1 Right?

2 A. Yes.

3 Q. You're evaluated on your communication skills, your  
4 leadership skills.

5 Correct?

6 A. Yes.

7 Q. You're evaluated on things like compliance.

8 Right?

9 A. Sure. Yeah.

10 Q. All right.

11 And you know -- and you were informed a few weeks ago  
12 that for the past two years, your evaluations on those  
13 nonsales metrics have been in the lower percentage of the  
14 sales reps.

15 Correct?

16 A. Yes.

17 Q. All right.

18 And as a result, you, like many others with the low  
19 evaluations, were put on a list.

20 Correct?

21 A. Yes.

22 Q. And that list was either for relocation or for work force  
23 reduction.

24 Correct?

25 A. I don't understand the work force reduction, but --

1 Q. Sure.

2 When you -- when you were put on that list, you had a  
3 meeting with HR.

4 Correct, ma'am?

5 A. Yes.

6 Q. And you raised some concerns about being put on this  
7 list.

8 Right?

9 A. Yes, I did.

10 Q. All right.

11 And HR informed you that you were on the list because  
12 your nonsales evaluations were minimal or moderate over the  
13 past two years.

14 Correct?

15 A. On that call, they didn't say that.

16 Q. But you've since come to understand that, ma'am?

17 A. Yes.

18 Q. Okay.

19 And you raised some concerns in that meeting.

20 True?

21 A. I did.

22 Q. In part, you raised concerns that you were on the list  
23 because of this lawsuit.

24 Right?

25 A. Yes.

1 Q. Okay.

2 And you know one of the protections that a Relator has  
3 when they file a lawsuit like this is you're protected from  
4 retaliation by the company.

5 Right, ma'am?

6 A. Yes. We're supposed to be.

7 Q. Right.

8 And one of the things after you got put on this list,  
9 you stopped checking your email.

10 Right?

11 A. Yes. They told me to stop working.

12 Q. Right.

13 And there was, in fact -- and we looked at it last  
14 week -- follow-up communication to you from Janssen that you  
15 weren't aware of.

16 Correct?

17 A. Correct.

18 Q. And it's already in evidence.

19 MS. BROWN: Let's just put it up there.

20 BY MS. BROWN:

21 Q. You didn't know that the head of human resources,  
22 Ms. Coleman, if we go down here at the bottom, had reached  
23 back out to you with an employment update on May 9th.

24 Correct?

25 A. I didn't know that, no.

1 Q. Okay.

2 You didn't know -- she said you were one of a number of  
3 employees that were notified about the end of employment in  
4 May.

5 Correct?

6 A. Yes.

7 Q. She said that this list was folks who had one or more  
8 moderate or minimal ratings under the company's performance  
9 metrics in 2022 and 2023.

10 Right?

11 A. Yes.

12 Q. And then she talked about how you had raised concerns  
13 about these ratings.

14 Right?

15 A. Yes.

16 Q. You were concerned, and you raised your hand and said it:  
17 Janssen, I don't think you're being fair to me,  
18 Ms. Brancaccio.

19 Right?

20 A. Not in those words, but yes.

21 Q. The gist of it.

22 A. The gist of it.

23 Q. Okay.

24 And so Janssen got back to you with an update and said,  
25 Okay. Let's have a conversation about it. We'll do these

1 three things. These are three options.

2 Right?

3 A. Yes.

4 Q. Number one, we're just going to take you off the list.

5 You can come back to work right now.

6 Right?

7 That was option one?

8 A. Yes.

9 Q. And you weren't aware of that when you testified.

10 Correct?

11 A. Correct.

12 Q. Number two, you could take that severance package.

13 Correct?

14 A. Yes.

15 Q. And you weren't aware that that severance package allows  
16 you to continue suing us in this case.

17 Right?

18 A. Correct.

19 Q. And number three, maybe you want another fresh start, and  
20 we could work together to try and find another spot for you in  
21 the family of companies.

22 Correct?

23 A. Yes.

24 Q. And you weren't aware -- and fair enough, ma'am, because  
25 you hadn't been checking your email -- that this

1 correspondence had come to you during the course of this  
2 trial.

3 Correct?

4 A. Correct.

5 Q. You've since had a chance to look at your email, ma'am?

6 A. I did look at this letter.

7 Q. Yes.

8 You've since had a chance to understand the options  
9 that are available to you?

10 A. Yes.

11 Q. You understand now that having started with us in 2003,  
12 having worked with us in HIV through 2020, having promoted  
13 cancer medicines with us through 2024, you have the  
14 opportunity to finish your career at Janssen.

15 Correct?

16 A. According to this, yes.

17 Q. Okay.

18 Are you going to take that opportunity?

19 A. I haven't made that decision yet.

20 MS. BROWN: No further questions, Your Honor.

21 THE COURT: All right. Thank you, Ms. Brown.

22 Mr. Wirmani, any redirect?

23 MR. WIRMANI: Yes, Your Honor.

24 (REDIRECT EXAMINATION BY MR. WIRMANI:)

25 Q. Ms. Brancaccio, we're going to talk about the employment



1 issue, but we're going to do it last. But I want to start  
2 with this question.

3 Did you believe that you had been terminated and that  
4 you no longer had a job at Janssen as of May -- excuse me --  
5 April 24th or 25th when you had that conversation or received  
6 that letter?

7 A. That's correct.

8 Q. And is the first time that you ever heard that Janssen  
9 had changed its mind when you were on this witness stand last  
10 Wednesday?

11 A. That's also correct.

12 Q. Okay. We're going to come back to that.

13 She asked you about journal clubs, and you talked about  
14 journal clubs on direct.

15 Correct?

16 A. Yes.

17 Q. And then she showed you an email where I believe  
18 Mr. Dolisi was saying, Well, we don't have journal clubs. And  
19 that was in 2011.

20 Correct?

21 A. Yes.

22 Q. At some point did the journal clubs stop?

23 A. Yes. We did -- we did conduct journal clubs, and then  
24 they stopped.

25 Q. Okay.

1 Was that before 2011?

2 A. Probably, yes.

3 Q. And you talked about notes that you kept as a  
4 salesperson. Are you talking about notes that you kept in  
5 real time back in 2006, '7, '8, '9, while you were selling the  
6 drugs Prezista and Intelence?

7 A. Yes.

8 Q. Okay.

9 Kind of like lawyers are passing notes around during  
10 this trial?

11 A. Exactly.

12 Q. And we, at the end of the day, roll those up, throw it  
13 away.

14 Correct?

15 A. Exactly. Yes.

16 Q. Is that what you did with your -- these notes that  
17 Ms. Brown thinks are so sinister?

18 A. Yes. They were just scrap pieces of paper --

19 MS. BROWN: Objection, Your Honor, to that.

20 THE COURT: Sustained.

21 MS. BROWN: Move to strike, please.

22 BY MR. WIRMANI:

23 Q. Did you throw those notes away before you filed this  
24 lawsuit and before you had any discovery obligations?

25 A. Yes.

1 MR. WIRMANI: Can I have the ELMO, please.

2 THE COURT: Sorry. Just so -- I'm doing the record  
3 on realtime. The move to strike, I don't think I responded,  
4 but it's denied.

5 But we'll continue.

6 BY MR. WIRMANI:

7 Q. Ms. Brancaccio, you were shown this screenshot on direct  
8 examination.

9 Correct?

10 A. Yes.

11 Q. Okay.

12 Is this an internal intranet that every employee at  
13 Janssen has access to?

14 A. Yes, it is.

15 Q. Do you have a page just like that that anybody within  
16 Janssen can access and look at?

17 A. Yes.

18 Q. Okay.

19 Does this have anything to do with your lawsuit, your  
20 allegations about off-label marketing or kickbacks?

21 A. No, nothing.

22 Q. Did you know that Janssen, as late as September of 2023,  
23 was taking your emails and monitoring what you were doing?

24 A. No, I had no idea.

25 Q. You said that you didn't have any issues with

1 Ms. Bartnett. Did any of those emails that Ms. Brown showed  
2 you -- did you express any hatred or animosity toward  
3 Ms. Bartnett?

4 A. No.

5 Q. Do you like Ms. Bartnett as a person?

6 A. Yeah. I think she's a nice person.

7 Q. Okay.

8 A. She's a mom just like I am. You know, we had discussions  
9 of things like that, so, yeah, we got along.

10 Q. But that is also the same Nancy Bartnett that we heard on  
11 that recording talking about Prezista having the same lipids  
12 as Reyataz, being lipid friendly and lying about what was in  
13 the guidelines.

14 Correct?

15 A. That's correct.

16 Q. If you had any issues with Ms. Bartnett, do they relate  
17 to the allegations in this suit and what happened at work or  
18 to personal things?

19 A. It's work. It's strictly work.

20 Q. You were repeatedly shown documents like this one, and  
21 you were asked about the name up at the top where it says,  
22 "Welcome, Nancy Bartnett."

23 Do you see that?

24 A. Yes.

25 Q. Okay.

1 Do you recall whether Ms. Bartnett gave her login  
2 information to everybody in the New York district so they  
3 could set up these speaker programs?

4 A. Yes, she did.

5 Q. Is that something that your co-Relator, Ms. Penelow,  
6 might also remember?

7 A. Yes, probably.

8 Q. You were shown Defendants' 8856.

9 Do you recall that?

10 A. Yes.

11 Q. And the questions that you received were about this  
12 binding affinity thing.

13 Correct?

14 A. Yes.

15 Q. I want to show you something. And we talked a lot about  
16 these documents that you got, and Janssen talked a lot about  
17 its own policies.

18 Correct?

19 A. Yes.

20 Q. Does that say that they're very important, "These slides  
21 support what the Government was asking us for at our last  
22 request"?

23 A. Yes, it does.

24 Q. And what does that next line go on to say?

25 A. "Slide 20 is binding affinity."

1 Q. Wait. Right after where I underlined, does it say, "How  
2 does HIV medication impact cardiovascular in HIV patients?"

3 A. Yes.

4 Q. Is that the lipid issue that we've been talking about  
5 throughout this lawsuit?

6 A. Yes, it is.

7 Q. So the Government wanted more information about that  
8 issue.

9 A. Yes, they did.

10 Q. You heard that recording with -- I believe his name was  
11 Ray, a science liaison?

12 A. Yes.

13 Q. Explain to the jury: What was the timeline? Was  
14 Nancy Bartnett always sending off-label requests from doctors  
15 to herself, or was there a time where she used the appropriate  
16 channels?

17 A. There were times that she used the appropriate channels.  
18 And in that conversation, she wanted Ray to talk to  
19 Dr. Turrett about the pipeline.

20 Q. Okay.

21 And I believe you testified on cross -- you were trying  
22 to explain different time periods.

23 Correct?

24 A. Yes.

25 Q. You were asked, if you wanted address information from

1 Ms. Bartnett, why didn't you just go to her lawyers?

2 Do you remember that?

3 A. Yes.

4 Q. Okay.

5 When Janssen decided to terminate you and asked you to  
6 waive your rights to this lawsuit, did they go to your  
7 lawyers?

8 A. No, they did not.

9 MR. WIRMANI: Can we bring up Defendants' 2297. I  
10 believe it's already in evidence.

11 BY MR. WIRMANI:

12 Q. And you were asked, Ms. Brancaccio, on your  
13 cross-examination about this email and some training  
14 requirements. We've looked at the second page of that.

15 And this is like a training module that you were  
16 required to take at Janssen.

17 Correct?

18 A. That's correct.

19 Q. And that's in 20- -- if we can put that back down -- is  
20 that dated 2013 on the first page?

21 Were you here in the courtroom when Mike Iacobellis  
22 testified that Janssen, in 2010, had to agree to a CIA based  
23 on conduct related to off-label marketing?

24 A. Yes, I was.

25 Q. And were you here in the courtroom when Mr. Iacobellis

1 said, in 2013, Janssen had to agree to a corporate integrity  
2 agreement related to off-label marketing?

3 A. Yes, I was.

4 Q. Do you know whether this training was required by those  
5 corporate integrity agreements?

6 A. Well, it says that it's required training on the top, on  
7 the subject line, so, yes.

8 Q. Okay.

9 In a lot of compliance emails and documents that we  
10 saw, a lot of them were, like, 2011, 2012, 2013.

11 Correct?

12 A. Yes.

13 Q. Remind the jury: How long has Janssen been engaging in  
14 kickbacks and illegal off-label marketing?

15 A. Since 2006.

16 Q. Okay.

17 So we didn't see training documents and things of that  
18 nature from '9, '10, '11, did we?

19 A. No, we didn't.

20 Q. Everything we saw was mostly after the corporate  
21 integrity agreement, the first one, was entered into by  
22 Janssen.

23 Fair?

24 A. That's right, yeah.

25 MR. WIRMANI: You can take that down.



1 BY MR. WIRMANI:

2 Q. You were asked about another drug called Complexra [sic].

3 Do you remember that?

4 A. Complera, yes.

5 Q. Complera, okay.

6 And I guess you were forwarded some study information  
7 on that drug. Is that a drug you sold?

8 A. Yes.

9 Q. Okay.

10 And Ms. Brown asked you if you, you know, if you ever  
11 marketed that drug off-label.

12 Do you remember that?

13 A. Yes.

14 Q. Did Mr. Dolisi or Ms. Bartnett or Frank Murphy, did they  
15 ever direct you to market that drug off-label?

16 A. They did not.

17 Q. Was Glenn Mattes still at the company when you guys were  
18 selling Complera?

19 A. I don't think so, no.

20 Q. Was Complera way, way, way behind on its forecast like  
21 Prezista was in 2006?

22 A. Not that I can recall.

23 Q. Did you receive the pressure to sell Complera, in the  
24 direction to sell illegally, that you did with respect to  
25 Prezista and Intelence?

1 A. No, we didn't.

2 Q. And you were asked repeatedly about not reporting, right,  
3 stuff within Janssen.

4 Do you recall that?

5 A. Yes.

6 Q. But you did report these allegations, didn't you?

7 A. Yes.

8 Q. Okay.

9 You reported them to the Government.

10 Correct?

11 A. Yes. Yes, we did.

12 Q. Who enforces the laws related to kickbacks and off-label  
13 marketing? Janssen or the Government?

14 A. The Government.

15 Q. And in your view, what is more effective when you see  
16 unlawful conduct: dropping a complaint in a red bag or going  
17 to the people that can actually do something about it?

18 A. Going to the people that can do something, the  
19 Government.

20 Q. What do you think would have happened if you had put a  
21 note in one of those little red bags that said, Janssen is  
22 engaged in a widespread, nationwide off-label marketing scheme  
23 and kickback scheme since 2006?

24 A. I would have fallen on -- it would have fallen on deaf  
25 ears. It wouldn't have been addressed.

1 Q. In fact, you testified that one of the reasons that you  
2 didn't report internally was because you saw what happened  
3 when people did.

4 Is that fair?

5 A. That's fair.

6 Q. Remind the jury what happened when you saw people that  
7 did report internally.

8 A. So, again, a woman named Joanne Sessario, she reported it  
9 internally, and she wound up getting fired.

10 Ms. Penelow reported it to human resources. She also  
11 reported it our superiors, our district manager, key account  
12 manager, and it also fell on deaf ears, and she was  
13 subsequently let go.

14 MR. WIRMANI: Can we bring up Defendants' 2276,  
15 please. It's already in evidence.

16 Can we publish to the jury.

17 BY MR. WIRMANI:

18 Q. And, ma'am, this is that email with Ms. Kaucher about  
19 these red bags.

20 Correct?

21 A. Yes.

22 Q. And what is the date there on that email?

23 A. November 8th, 2012.

24 MR. WIRMANI: And could we expand that down.

25 BY MR. WIRMANI:

1 Q. And Ms. Kaucher, down in that second email, do you see  
2 the third line where she is saying, "The red bag concept seems  
3 to be well received"?

4 A. Yes.

5 Q. Okay.

6 Is it your understanding that these red bags were first  
7 placed out around Janssen in 2012?

8 A. Yes.

9 Q. Okay.

10 Again, after the first corporate integrity agreement?

11 A. Yes.

12 Q. And those red bags didn't stop Janssen from having a  
13 second corporate integrity agreement, did they?

14 A. No, they didn't.

15 MR. WIRMANI: You can take that down, Ms. Johnson.

16 BY MR. WIRMANI:

17 Q. You were shown a list of doctors. And Ms. Brown asked  
18 you why none of those doctors came forward and reported  
19 illegal off-label marketing or kickbacks.

20 Do you remember that?

21 A. Yes.

22 Q. Okay.

23 And I believe you started to answer, and you said  
24 something to the effect of they didn't know. Can you explain  
25 to the jury what you meant by that?

1 A. So what I meant was that the physicians, the providers  
2 that we talked to, they didn't know when we were talking to  
3 them about an off-label study versus what was on-label in the  
4 package insert.

5 So we talked to them off-label, and they didn't -- they  
6 didn't know that that was not in the package insert.

7 Q. And remind the jury, how did you use the off-label  
8 studies? Did you just give them the off-label studies so they  
9 knew it was off-label, or did you look at conclusions?

10 A. We just went to the conclusion or the result of the study  
11 and verbalized it to them. We -- we had it. We -- we would  
12 show it, and we would take it back.

13 Q. Ma'am, you've been in sales a long, long time.

14 Is that fair?

15 A. Yes.

16 Q. Do you agree that, when people are being sold something,  
17 they don't always know that they're being influenced?

18 A. Yes.

19 Q. Isn't that one of the jobs of a salesperson, is to  
20 influence without directly overtly doing so?

21 A. Yes. That's part of the job, to influence them. That's  
22 what we get paid for.

23 Q. And you were asked about your deposition and the  
24 allegations regarding treatment-naive patients in Intelence.

25 Do you remember that?

1 A. Yes.

2 Q. Ms. Brown pointed out, Well, Ms. Graham, she didn't  
3 remember that.

4 Do you recall that?

5 A. Yes.

6 Q. You were in the courtroom when Ms. Graham testified.  
7 Correct?

8 A. Yes.

9 Q. Let me ask you this: If it has been suggested there is  
10 some sort of collusion and everybody is making this up,  
11 wouldn't you expect everybody's story to be the same?

12 A. You would expect that, yeah.

13 Q. But Ms. Graham, she didn't remember an experience that  
14 you had?

15 A. Right.

16 Q. Okay.

17 And if there was some kind of collusion, you'd expect  
18 that Mr. Wilhelm would have told Ms. Graham, Remember to talk  
19 about the once-daily Intelence, wouldn't you?

20 A. Yes.

21 Q. Mr. Wilhelm, do you recall if he testified about  
22 once-daily Intelence being marketed illegally off-label?

23 A. Yes.

24 Q. Okay.

25 And Ms. Graham, who we've repeatedly heard lives with

1 Mr. Wilhelm, she did not testify to that, did she?

2 A. No, she didn't.

3 Q. Do you remember Sara Strand testified about illegal  
4 marketing of Intelence once a day?

5 A. Yes.

6 Q. And those allegations -- you were deposed in 2019.

7 Correct?

8 A. Yes.

9 Q. Okay.

10 And we're going to get to the deposition, but it sounds  
11 like you forgot and then you came back and something, you  
12 know, got your memory going.

13 Is that fair?

14 A. That's fair.

15 Q. Okay.

16 But did those allegations -- did they appear in your  
17 live complaint in this case that was filed in 2017?

18 A. I'm sorry. Can you repeat that?

19 Q. Those allegations of off-label selling of Intelence once  
20 a day --

21 A. Yes.

22 Q. -- are those allegations in the live complaint in this  
23 case that was filed two years before your deposition?

24 A. Yes.

25 MR. WIRMANI: Can we bring up the live complaint in

1 this case just for the witness?

2 We're going to mark that as Relators' 1708.

3 (Relators' Exhibit 1708 for identification.)

4 MR. WIRMANI: And can we go to paragraph 45 and 46 on  
5 page 42 and 43, please.

6 Your Honor, at this time, I would offer the complaint  
7 as a prior consistent statement.

8 MS. BROWN: I object, Your Honor. It's hearsay.

9 MR. WIRMANI: It's not being offered for the truth,  
10 Judge. It's being offered as a prior consistent statement.

11 THE COURT: Let me see counsel at sidebar.

12 (Sidebar begins at 12:03 p.m.)

13 THE COURT: All right. So you're not offering it for  
14 the truth. You're offering it just to say she has said this  
15 in the past?

16 All right.

17 Then what is your objection?

18 MS. BROWN: It's hearsay, Your Honor. The complaint  
19 is hearsay. It's an out-of-court statement. She didn't even  
20 make it. It was filed by lawyers.

21 They moved to exclude the first version of the  
22 complaint, and now they're focusing on the second version of  
23 the complaint. If he wants to ask about what is in the  
24 complaint, I'm not objecting, but the complaint itself is  
25 hearsay.



1 THE COURT: Let me ask you this -- this is on a  
2 different topic but related to something that came up earlier.

3 You're allowed to -- you're introducing the second  
4 amended complaint. You're attempting to indicate to this jury  
5 that, prior to a particular year, she made some allegations  
6 that's consistent with what she said.

7 How does that then stop if you want to move this in  
8 from Janssen and say this is a second amended complaint? I  
9 want to talk about what's in the prior complaint. I want to  
10 go back to that issue, but that never met -- that never got in  
11 the complaint.

12 You spent a lot of time trying to keep that out, and  
13 I'm concerned that if you want to move in a complaint, which  
14 is a strange piece of evidence to move in the case, that I  
15 might allow it with the caveat that you just opened the door  
16 to every other thing that's in there, including everything  
17 that she didn't put in there.

18 Do we really want to go back in time on that issue?

19 MR. WIRMANI: It is the live complaint, so I don't  
20 think it violates the motion in limine, Your Honor, but if you  
21 believe that opens the door to prior complaints on all these  
22 issues, then I'm happy to just ask her about it.

23 THE COURT: Yeah. I mean, look, I would say  
24 normally, though, my practice -- let me ask you this, though:  
25 When you normally have a trial, does the charging document,

1 the complaint, the pleading, go back with the jury as a  
2 blueprint?

3 MS. BROWN: Never. I've never had that in any case  
4 I've tried.

5 MR. WIRMANI: It's supposed to be read to the jury  
6 just like the indictment charge, Judge.

7 THE COURT: Yeah. And so it's a lot of different --

8 MS. BROWN: I don't do criminal work. In civil  
9 trials, no.

10 THE COURT: Yeah. So here's my only concern, then.  
11 I'm going to deny it.

12 Let me ask you this: If I say -- I'm just curious,  
13 Mr. Wirmani, I'll allow it in, but I'm going to let Janssen go  
14 back into what is in the first amended complaint, what is in  
15 the initial complaint and anything she's written about, that  
16 she's complained about that's not in the complaint, which you  
17 tried to block. Do you still want to move this in, because  
18 that's where I'm inclined to go?

19 MR. WIRMANI: I would ask, Judge, that I be allowed  
20 to show just the witness, as she did with many documents, and  
21 ask her questions in that fashion without admitting it,  
22 without publishing it to the jury.

23 THE COURT: If she's reading off of the document,  
24 you're doing it through the back door, right?

25 So in other words, you can show a witness -- if your

1 only goal is to say, Did you make this allegation in your  
2 complaint in this case and she says, Yes, move on.

3 Now, if she says, I can't remember, then you can show  
4 it to her. You don't get to say, Read me paragraph 9, which I  
5 have a problem with, and that's happened in the past but  
6 that's because there's been no objection.

7 But if you say, Does that refresh your recollection as  
8 to what you raised in the complaint and she says, yes; and did  
9 you raise it, I did; then I will tell you you can do that.  
10 That's as far as we go.

11 MS. BROWN: Yeah. I mean, those three questions I  
12 have no problem with. If it's, Isn't it true in this second  
13 amended complaint you said this and that's consistent with  
14 what you told our jury, that is opening the door to it being  
15 inconsistent with the first amended and the original.

16 So if we just stop at the second amended complaint says  
17 this, I have no objection. If it goes beyond that, then I  
18 think he opens the door to what he's trying to explain.

19 THE COURT: Well, let me just ask: Now that we've  
20 gone through this whole dialogue, what do you intend to get  
21 out? Let me hear basically what the question is.

22 MR. WIRMANI: So there's detailed allegations in that  
23 complaint about this issue of marketing Intelence unlawfully  
24 once a day.

25 I'd like to ask her if she referenced the studies that

1 were used, if she referenced people that were involved, if she  
2 referenced how many paragraphs that it encompassed. Just  
3 that.

4 That is -- that is a prior consistent statement that is  
5 directly responsive to the impeachment that Ms. Brown did, and  
6 I'm not going to go beyond that.

7 MS. BROWN: May I just offer a suggestion to help  
8 you? The issue she forgot was naive, not once a day. So if  
9 we're focusing on once a day, everybody agrees she knew that  
10 one. What she forgot was --

11 THE COURT: All right. If you're asking her whether  
12 she made that allegation in the complaint in this case and she  
13 wants to say yes, I'm okay with that. I wouldn't go too far  
14 beyond that.

15 I'm going to deny your ability to admit the document.  
16 That's where we are.

17 (Sidebar was concluded at 12:07 p.m.)

18 (Open court.)

19 MR. WIRMANI: Can I have just one second, Judge?

20 THE COURT: You may.

21 (Brief pause.)

22 BY MR. WIRMANI:

23 Q. Ma'am, did -- the live complaint was filed in 2017.

24 Correct?

25 A. Yes.

1 Q. That is two years before you were deposed in this case?

2 A. Yes.

3 Q. Did that complaint contain allegations -- in fact both  
4 allegations of off-label marketing, illegally once a day to  
5 naive patients for the drug Intelence?

6 A. That's correct.

7 Q. Did that complaint reference the DeJesus study that you  
8 testified on direct was used in the course of that illegal  
9 marketing of Intelence once a day and for naive patients?

10 A. Yes, it does.

11 MR. WIRMANI: And just for the witness, can we go to  
12 page -- paragraph 46 and 7? Page 44, paragraph 152. I  
13 apologize.

14 BY MR. WIRMANI:

15 Q. And in that complaint that was filed in 2017, two years  
16 before your deposition, did you talk about numerous  
17 salespeople and managers also using these approaches to  
18 promote Intelence for treatment-naive parents across the  
19 nation?

20 A. Yes, I did.

21 MR. WIRMANI: You can take that down, Ms. Johnson.

22 BY MR. WIRMANI:

23 Q. And can we -- you recall a portion of your deposition was  
24 played on cross-examination.

25 Correct?

1 A. Yes.

2 Q. There was an objection, and it was incomplete, and the  
3 judge said I'd have a chance on redirect to play the  
4 additional portions of the deposition so the jury can have  
5 context.

6 Do you recall that?

7 A. Yes.

8 Q. Rather than play it, I'm just going to read it with you.

9 MR. WIRMANI: May I approach, Judge.

10 THE COURT: You may.

11 BY MR. WIRMANI:

12 Q. Ms. Brancaccio, I'm handing you a copy of your sworn  
13 deposition that you gave in 2019 in this case.

14 MS. BROWN: Can I just know what page?

15 THE COURT: Yeah. Where are we if it's a transcript?

16 MR. WIRMANI: I'm about to direct her, Judge.

17 And could we go to page 258, starting at line 18.

18 MS. BROWN: Your Honor, I don't have a copy. Can I  
19 just grab a copy? I'm not sure where counsel is going.

20 THE COURT: Yes.

21 Counsel, for some reason we can't just play that  
22 portion?

23 MR. WIRMANI: I don't believe we have the video cued  
24 up, Judge.

25 THE COURT: Got it. Well, then just give it a moment

1 because I want to make sure counsel has it.

2 MR. WIRMANI: Yeah.

3 MS. BROWN: I'm sorry. What's the page and line?

4 MR. WIRMANI: Starting at 258, line 18, going to  
5 page 259, line 9.

6 MS. BROWN: I have no objection.

7 THE COURT: All right.

8 MR. WIRMANI: Permission to publish this to the jury,  
9 Judge.

10 THE COURT: You may.

11 BY MR. WIRMANI:

12 Q. Ms. Brancaccio, I'm going to show you -- do you recall  
13 the video playing when you came back from the break and  
14 Mr. Watson was asking you some questions?

15 A. Yes.

16 Q. And I'm just going to read these questions to you and ask  
17 you to just do the answer with me.

18 Okay?

19 A. Sure.

20 Q. So Mr. Watson says:

21 "So you're adding something new to your answer to my  
22 prior question?"

23 A. "I'm adding -- I'm adding something additional to it."

24 Q. "Did you discuss that with counsel during the break?"

25 A. "I remembered that -- it hit me."

1 Q. "That's not my question."

2 Do you see that?

3 A. Yes.

4 Q. "Did you discuss my question and your prior answer with  
5 counsel during the break?"

6 A. "I did because I" --

7 Q. "Did they remind you to say treatment-naive?"

8 A. "No. I remembered that" --

9 MS. BROWN: Can we have the next line and answer,  
10 Your Honor, for completeness?

11 THE COURT: Let me see counsel at sidebar.

12 (Sidebar begins at 12:13 p.m.)

13 THE COURT: So you have to do it now. What happened  
14 is there was an objection to completeness.

15 The only thing that I changed was that she doesn't have  
16 to put it in because you can put the whole thing in. If  
17 you're not putting the whole thing in, I got to put the whole  
18 thing in because that was the objection.

19 MR. WIRMANI: That's fine.

20 THE COURT: How far do you want it to go?

21 MS. BROWN: So 10 through 13. We discussed it with  
22 counsel.

23 (Sidebar was concluded at 12:13 p.m.)

24 (Open court.)

25 BY MR. WIRMANI:



1 Q. Ms. Brancaccio, after line 9 there, there's a question:  
2 "You discussed the question and answer with counsel during the  
3 break?"

4 And your response is, "Yes, because I questioned that  
5 myself as what you meant by 'training.'"

6 Do you see that?

7 A. Yes.

8 Q. Okay.

9 And, Ms. Brancaccio, clearly you discussed this issue  
10 with counsel during the break.

11 But my question is: Did counsel suggest to you that  
12 you should testify about illegal marketing of treatment-naive  
13 patients?

14 A. They did not.

15 Q. Did they remind you of that issue?

16 A. No.

17 Q. And is that what you testified to in your deposition?

18 A. Yes.

19 Q. Ms. Brancaccio, I want to take you back to last Wednesday  
20 when you were first on the witness stand with Ms. Brown.

21 Okay?

22 A. Sure.

23 Q. Ms. Brown, throughout her testimony both on Wednesday and  
24 today, kept using the phrase "when you sued us," meaning  
25 Janssen.

1 Do you recall that?

2 A. Yes.

3 Q. Did you personally sue Janssen for some personal claim,  
4 or did you blow the whistle for tax -- the whistle for  
5 taxpayers?

6 A. We blew the whistle for taxpayers.

7 Q. And is this a personal lawsuit about some injury that you  
8 have personally suffered?

9 A. No.

10 Q. Who are the victims in this case?

11 A. The Government.

12 Q. Now, you testified -- I mean, I think you were on cross  
13 for about five hours.

14 Does that sound about right?

15 A. Yes.

16 Q. And on direct, we talked for about two hours about your  
17 experience and what you saw and what you observed in the field  
18 related to illegal kickbacks and illegal off-label marketing.

19 Correct?

20 A. Yes.

21 Q. Did Ms. Brown ask you many questions about that actual  
22 testimony on direct?

23 A. Not that I can recall.

24 Q. Were the vast majority of her questions about how you got  
25 the evidence showing Janssen's misconduct rather than about

1 the misconduct itself?

2 A. Yes.

3 Q. Do you know -- you've been in this process for 12 years.

4 Correct?

5 A. Yes.

6 Q. Do you know whether under federal law you, as a  
7 whistleblower, are protected --

8 MS. BROWN: Objection, Your Honor.

9 THE COURT: Hold on. Sidebar.

10 (Sidebar begins at 12:16 p.m.)

11 THE COURT: It sounds like you're about to go into  
12 the subject matter that I reserved on. So what were you about  
13 to ask?

14 MR. WIRMANI: I would like to know whether she  
15 understands --

16 THE COURT: No. It's the same thing as -- this is  
17 the very issue that I said we're not going to put before this  
18 jury because I reserved on this.

19 So your solution to that is, Instead of reserving,  
20 Judge, I'm going to have her tell me what I want to say,  
21 which, by the way, leading questions the entire afternoon, but  
22 you haven't said anything, so we're moving forward.

23 No.

24 MR. WIRMANI: Understand.

25 THE COURT: Sustained.

1 (Sidebar was concluded at 12:16 p.m.).

2 (Open court.)

3 BY MR. WIRMANI:

4 Q. Ma'am, do Janssen's policies -- do they trump federal  
5 law, as far as you know?

6 MS. BROWN: Objection, Your Honor. Same objection.

7 THE COURT: Sustained.

8 MR. WIRMANI: Let's bring up 8658. This can be  
9 published to the jury.

10 BY MR. WIRMANI:

11 Q. Ma'am, you were asked a number of questions about these  
12 MedForce tracking documents.

13 Do you recall that?

14 A. Yes.

15 Q. And I want to take a look at this amendment with you.

16 MR. WIRMANI: Could we go to page 2, please.

17 BY MR. WIRMANI:

18 Q. If you look at that bottom email, that is from  
19 Ananda Chaudhuri, and it looks like that's a -- that's a  
20 lawyer.

21 Correct?

22 A. Yes.

23 Q. Okay.

24 And that's an email that goes to Ms. Joy Clairmont, who  
25 was one of your lawyers back during this time period.

1 Correct?

2 A. Yes.

3 Q. And to you?

4 A. Yes.

5 Q. And Mr. Chaudhuri says in the second paragraph, "Also,

6 John Crouse asked if she knew what Segal-Maurer made per

7 speaker conference and how many conferences she did.

8 Christine told me that this information was on the database

9 she accesses on a regular basis for her job, and she can

10 provide this information to him."

11 Okay.

12 Do you remember whether Mr. Crouse was an assistant to

13 the United States attorney?

14 A. Yes.

15 Q. He was?

16 A. I believe he was with the Government, yes.

17 MR. WIRMANI: You can take that down.

18 BY MR. WIRMANI:

19 Q. We talked about MIRs and, you know, just let me ask you

20 this: Did you illegally solicit more than one MIR?

21 A. Yes.

22 Q. Was that practice unique to you or widespread at Janssen?

23 A. It was a widespread practice at Janssen.

24 Q. And there was a suggestion that maybe this all came up

25 just right before the lawsuit.

1 When did that practice start?

2 A. That practice started years ago. It started -- MIRs were  
3 started in 2006, and the MIR process was to disseminate the  
4 off-label information through an MIR process.

5 First, we could get that MIR sent to ourselves, as  
6 sales representatives, get them morphed into getting MIRs to  
7 the providers out in the field and asking -- having them ask  
8 for off-label information, solicit that information and then  
9 it went to Nancy Bartnett, taking those MIR questions  
10 verbally, and there was nothing written.

11 Q. And at all times when you or others were engaged in that,  
12 was that direction and instruction coming from your  
13 management?

14 A. Yes.

15 Q. Who were those individuals?

16 A. Frank Murphy, Nancy Bartnett, Tony Dolisi.

17 Q. Ms. Brown showed you last week on Wednesday a speaker  
18 slide deck that had off-label slides.

19 Do you recall that?

20 A. Yes.

21 Q. Just let me ask you one question: Did you do anything to  
22 that document other than maybe open it and then pass it on to  
23 your lawyers?

24 A. I opened it, and I passed it on.

25 Q. Okay.

1           Look at the jury. Tell them: Did you modify that  
2 document in any way?

3 A. I did not modify it. I'm not that computer savvy. I did  
4 not modify it whatsoever.

5 Q. Now, Ms. Brown, she did not ask you about the actual  
6 content of the presentation again.

7           Correct?

8 A. No.

9 Q. Okay.

10           Tell the jury, what does that slide deck show?

11 A. So I recall it was an Intelence slide deck, and it  
12 showed -- there was -- there were off-label slides embedded in  
13 the entire speaker deck so that, when the provider went and  
14 talked to the audience, she would go through those off-label  
15 slides for -- it was all -- it was all Intelence related.

16           It was Intelence on-label and off-label for once a day  
17 as well as naive.

18 Q. And why did you feel that you needed to get those as part  
19 of this case?

20 A. Because I knew that -- I knew that they would lie,  
21 basically, that Janssen would lie and say, No, that never  
22 happened, so I had to have proof to say that we're telling you  
23 the truth.

24 Q. And did Ms. Brown question you last week about -- again,  
25 not federal or state law, but Janssen's own policies and

1 violating those policies with respect to making a recording of  
2 Ms. Bartnett and Dr. Turrett?

3 A. Yes.

4 Q. But did you recall her also asking you if that was the  
5 only recording of a doctor that you had?

6 A. Yes.

7 Q. Did Ms. Brown talk in opening -- you were here for  
8 opening.

9 Correct?

10 A. Yes.

11 Q. Did she talk in opening about the Relators not having any  
12 documents to support their case?

13 A. Yes.

14 Q. Okay.

15 Then did she also question you extensively about  
16 Janssen's policies and how you got the documents that we've  
17 been showing the jury, at least some of them?

18 A. Yes.

19 Q. Did Ms. Brown, during opening, suggest that there was  
20 something wrong with getting declarations?

21 A. Yes, she did.

22 Q. Did she also question you on cross-examination about why  
23 you didn't get more declarations, including from every one of  
24 your co-workers in the New York district?

25 A. Yes.



1 Q. And she said that that recording of Dr. Turrett -- she  
2 says that's the only evidence that this jury is going to see  
3 of how a doctor makes decisions from the Relators.

4 Do you recall that?

5 A. Yes.

6 MS. BROWN: Your Honor, I object to that. It  
7 misstates.

8 THE COURT: Sustained.

9 BY MR. WIRMANI:

10 Q. Were you in the courtroom when Mike Iacobellis was shown  
11 marketing surveys that Janssen paid for that asked doctors  
12 what factors and what messages resonated with them?

13 MS. BROWN: Your Honor, I object to leading.

14 THE COURT: Sustained.

15 BY MR. WIRMANI:

16 Q. Do you recall Mike Iacobellis's testimony?

17 A. Yes.

18 Q. Okay.

19 Did -- was he shown documents about marketing?

20 A. Yes.

21 Q. Were those documents, according to Mike Iacobellis's  
22 testimony, were they documents that Janssen paid for or that  
23 Janssen received for free?

24 A. They paid for them.

25 Q. Okay.

1           And were there -- when we looked at the bottom of those  
2 documents, did we see questions that doctors were answered  
3 [sic] -- that --

4           MS. BROWN: Same objection, Your Honor.

5           THE COURT: Sustained.

6 BY MR. WIRMANI:

7 Q. Did those documents talk about some of the same off-label  
8 messages that we've been discussing in this case?

9 A. Yes.

10          MS. BROWN: Same objection.

11          THE COURT: Sustained. You've got to -- it's form  
12 over substance, but it's got to be direct. It's got to be  
13 open-ended.

14 BY MR. WIRMANI:

15 Q. Have -- you've been in the courtroom. Have witnesses  
16 talked about, including yourself, what doctors told them when  
17 they were out in field?

18 A. Yes.

19 Q. And do you have experts, do the Relators have experts  
20 that are going to come testify about these issues, about what  
21 influences doctors?

22 A. Yes, I believe so.

23 Q. Ms. Brown made a big deal on that tape of kind of  
24 ignoring the lipid issue but pointing out that there was no  
25 discussion of once-daily dosing of Intelence.

1 Do you recall that?

2 A. Yes.

3 Q. Did you hear the part of the tape where Dr. Turrett said  
4 he got burned on QD-Intelence?

5 A. Yes.

6 Q. Do you know what he meant by that?

7 MS. BROWN: Objection, Your Honor. Speculation.

8 MR. WIRMANI: She was there.

9 THE COURT: What did you understand it to mean? What  
10 did you understand what he said to mean?

11 THE WITNESS: It sounds like he tried it on a patient  
12 and that it -- the patient did not do well for whatever  
13 reason.

14 BY MR. WIRMANI:

15 Q. And when Ms. Bartnett was -- you were present for this  
16 conversation, correct?

17 Remind the jury.

18 A. Yes, I was there.

19 Q. When Ms. Bartnett was talking about Prezista and Reyataz  
20 and how the lipids were the same, did anything about that  
21 conversation have to do with dosing and the dosing making the  
22 lipids the same?

23 A. No, there was nothing about dosing during that.

24 Q. You testified that it was okay to compare doses of  
25 medicine. Explain to the jury what that means. How can you

1 do that?

2 A. If you're talking about Prezista and Reyataz, you can say  
3 that Prezista can be dosed twice a day and that Reyataz can  
4 also be dosed once a day or twice a day. Whatever the dosing  
5 schedule is on-label, you're allowed to talk about that.

6 Q. And did you hear that type of conversation on that tape  
7 from Ms. Bartnett?

8 A. No, there was nothing.

9 MR. WIRMANI: Can we bring up Defendants' 6028? It's  
10 already been admitted into evidence. It can be published to  
11 the jury.

12 BY MR. WIRMANI:

13 Q. Ms. Brancaccio, we've looked at this email several times.  
14 Correct?

15 A. Yes.

16 Q. And just to be clear, this was intended to be a  
17 privileged conversation between you and Ms. Penelow and your  
18 counsel.

19 Correct?

20 A. Correct.

21 Q. And the only reason that we can see it and Janssen has it  
22 is because Ms. Penelow decided to forward it to her mother.

23 A. Correct.

24 Q. And then during discovery in this case, Janssen demanded  
25 that it be turned over.

1 Correct?

2 A. Yes.

3 Q. And, Ms. Brancaccio, is there anything about this email  
4 that you're embarrassed about or anything was wrong?

5 A. No.

6 Q. If one of your private emails with your lawyer was going  
7 to be shown to a jury, is there anything more than that you  
8 would want it to say than this email says?

9 A. No. It says nothing, really.

10 Q. Does Ms. Clairmont repeatedly emphasize the need to be  
11 truthful and accurate and to review the information yourself?

12 A. Yes, she does it over and over again.

13 Q. In fact, she says, "If we've gotten any facts wrong or  
14 omitted anything important, please let us know."

15 A. Yes.

16 Q. Okay.

17 And if we go down to the bullet number 3, the dinner  
18 programs and the speaker programs, does Ms. Clairmont say that  
19 before she even sent this email, the one area of the complaint  
20 where she needs work is the dinner/speaker program section?  
21 "We need a discussion of these programs to show how J&J  
22 off-label promotion was delivered nationwide."

23 Based on what you read there or -- and what you recall,  
24 were the allegations about the speaker program, were they  
25 already in the complaint before this email was sent?

1 A. Yes. We had discussed it.

2 Q. And she's asking you for additional details.

3 Fair?

4 A. Yes.

5 Q. Including -- including some things about the nature of  
6 the programs, the purpose of selection, information that was  
7 disseminated at these programs.

8 Fair?

9 A. Yes.

10 Q. Remind the jury: How many did you personally attend?  
11 How many speaker programs did you personally attend?

12 A. Over the years, I've -- I couldn't even put a number on  
13 it. There were a lot that I attended throughout the New York  
14 area.

15 Q. Are you glad that when your lawyers would communicate  
16 with you they would ask you to be truthful and accurate and  
17 ask what is correct and incorrect and ask for further details  
18 before they decided to go forward with a claim?

19 A. Yes.

20 MR. WIRMANI: Again, if we can expand that back down.

21 BY MR. WIRMANI:

22 Q. Remind the jury: When you first went to counsel in 2012,  
23 did you raise concerns about the speaker payments and the  
24 tracking of the doctors' prescriptions?

25 MS. BROWN: Your Honor, may we approach on this

1 question?

2 THE COURT: Sure.

3 (Sidebar begins at 12:29 p.m.)

4 MS. BROWN: I think he is waiving privilege on these  
5 discussions with the lawyers, and that's fine. But I just  
6 wanted to come up and talk to the Court because there are  
7 going to be documents that -- if he asked this question, Did  
8 you discuss this with your lawyer prior to filing the  
9 complaint? There are documents they've withheld that I think  
10 we're entitled to. So how can I check the veracity of that if  
11 they withheld the documents --

12 THE COURT: I understand the point.

13 Let me hear from Mr. Wirmani about it.

14 MR. WIRMANI: I believe she's already testified to  
15 this on direct and there was no objection or no question that  
16 privilege had been waived, Your Honor.

17 And, obviously, I'm allowed to ask about this  
18 particular document. She's using it to suggest that there was  
19 something nefarious, that lawyers are making kickback  
20 allegations, and that's all I want to ask her, is just, you  
21 know, to reconfirm what she said on direct, which is she had  
22 these concerns before she went to lawyers.

23 And I can actually ask it just like that.

24 MS. BROWN: That question I don't have an objection  
25 to.

1 THE COURT: I'm okay with that question, too,  
2 Ms. Brown. But you understand --

3 MR. WIRMANI: I understand.

4 THE COURT: I'm concerned with that, too. So let's  
5 go that way, and then move forward.

6 (Sidebar was concluded at 12:31 p.m.)

7 (Open court.)

8 BY MR. WIRMANI:

9 Q. But let me -- so, ma'am, let me rephrase. Let me ask it  
10 like this.

11 Did you have concerns about the speaker payments being  
12 inducements to doctors long before you went to counsel in this  
13 case?

14 A. We had it long before.

15 Q. Okay.

16 And, again, you're not a lawyer.

17 A. No.

18 Q. Okay.

19 And is it your understanding that the proper way to  
20 work with a lawyer is you give them the facts and then they  
21 give you the law?

22 A. Yes.

23 Q. Is that the way it always happened here?

24 A. That's the way we always -- this is the way it always  
25 was, from day one.



1 Q. Thank you.

2 MR. WIRMANI: Judge, I probably have 20 more minutes,  
3 15 more minutes. So I don't know if you want me to go or if  
4 you want me --

5 THE COURT: Well, we can just -- and if you want to  
6 break for lunch, and then we will do the 20 minutes when we  
7 come back. It's hard to tell, because I'm going to get this  
8 and I'm going to get this.

9 Here's what we're going to do. Nobody's going  
10 anywhere, so we'll just break for lunch, and then why don't  
11 you complete the 20 minutes or so as soon as we get back.

12 I do need to speak with counsel, though, on a few  
13 issues when we dismiss the jurors. So let's do that.

14 Let's get the jurors dismissed for lunch, and then  
15 we'll go from there.

16 THE DEPUTY COURT CLERK: All rise.

17 (Jury exits the courtroom.)

18 THE COURT: All right, folks. Have a seat.

19 Ma'am, you can come off the witness box as well.

20 Just three quick things. One is come back early from  
21 the lunch. So if I give you 45 minutes, when you're done,  
22 come back because I want to speak about the trial schedule,  
23 but let's do that after you all eat. But I need to condense  
24 the schedule even more for you.

25 So if you guys were not happy with what I did before,

1 I'm going to tighten it a little bit more, but we'll see where  
2 we are.

3 Second issue that I want to talk about is just be  
4 careful on questions of the law, folks, because that's my  
5 purview with the jury instructions. All right. So I just  
6 want you to be mindful of that. When you start asking folks  
7 questions about the law, that really should be in the jury  
8 instructions. Either you've already proposed them to me with  
9 some disputes that I have to resolve before the conclusion of  
10 the trial, or you believe that something has arisen during the  
11 trial that would warrant an additional final instruction that  
12 we're going to need to chat about.

13 The third piece that I don't think we spoke about this  
14 morning, but I just want to close the loop on it -- and I  
15 don't know if this is from Mr. Marketos or Mr. Wirmani, but  
16 there was -- I kind of left open last week that if you wanted  
17 to talk about the last modified that came in through  
18 testimony -- you guys didn't ask for anything, and it sounds  
19 like you did what you needed to do on redirect. So I'm  
20 presuming that that issue is closed, not that I still have  
21 that before me.

22 Am I correct in that assessment?

23 MR. MARKETOS: That's right, Your Honor, except  
24 that -- with one exception. If we get an argument from  
25 counsel at any time that data was manipulated, then we may

1 have to revisit --

2 THE COURT: Yeah, but they can't argue that, not  
3 based on the evidence that's currently before the trial. And  
4 I've already instructed Ms. Brown on that, that there's  
5 insufficient evidence to make that leap. So I think we're  
6 good on that, but I just wanted to make sure because we didn't  
7 speak about it that we close the loop.

8 Let me also just give you a heads-up of where I'm going  
9 with the trial schedule so you can think about it during lunch  
10 and then be upset with me either more or less -- is I want the  
11 jury to have the case by the 14th. That is still beyond the  
12 scope of the time frame that we gave them, but here's why --  
13 and also maybe we can go off the record so I can let Megan  
14 take a break.

15 Any reason why we can't speak off the record, just on  
16 trial scheduling?

17 MR. MARKETOS: No, that's fine, Your Honor.

18 MS. BROWN: No, Your Honor.

19 (Luncheon recess was taken from 12:35 p.m. until 1:24  
20 p.m.)

21 THE DEPUTY COURT CLERK: All rise.

22 THE COURT: Remain seated.

23 Why don't we talk about the trial scheduling after we  
24 get witness testimony. So maybe on the first stretch or  
25 something like that.

1 Does that make sense?

2 MS. BROWN: Sure.

3 THE COURT: I have at least some feedback. I had Kim  
4 speak to the jurors just to make sure they can even do  
5 Fridays. I don't know if people are working or what. So I  
6 got some assessment from them.

7 So want to get Ms. Brancaccio on the witness stand?

8 MR. MARKETOS: Yes, Your Honor. Sounds good.

9 THE COURT: And on the stretch break, let's chat a  
10 little bit about trial schedule, because nothing is being  
11 impacted today. It's going to be moving forward. So I'll  
12 talk to you a little bit more about that, and also where the  
13 jurors were with extending to 5 p.m. and where they were on  
14 certain Fridays, what they're able to do just because of  
15 employment and things of that nature. Okay.

16 Ms. Brancaccio, you're there.

17 Kim, you want to get the jurors.

18 THE DEPUTY COURT CLERK: All rise.

19 (Jury enters the courtroom.)

20 THE COURT: All right, folks. Everybody have a seat.

21 Just briefly for the jury, I am working on adjusting  
22 the trial schedule because the case is taking longer than  
23 anticipated. I have some feedback from you all that you gave  
24 to Kim, which I appreciate. I'll deal with that later today  
25 since nothing is changing today, so there's no reason for us

1 to slow up witness testimony.

2 But one thing that I will just alert you to is if  
3 you're all able to do 9:15 in the box, then tomorrow morning  
4 be ready at 9:15. And even if we have those extra 15 minutes  
5 each day, I'll take it.

6 So that one I want to give you now. As far as any  
7 other adjustments, I can always wait to tell you tomorrow  
8 morning, but we are going to work on some of those things that  
9 you provided feedback for, but I need time to speak with  
10 counsel.

11 So with that, Mr. Wirmani, are you able to continue  
12 redirect examination at this time?

13 MR. WIRMANI: Yes, Your Honor.

14 THE COURT: All right. Ms. Brancaccio, I know I've  
15 said this before. I'll just remind you that you're still  
16 under oath from earlier today.

17 THE WITNESS: Yes, sir.

18 THE COURT: You may proceed.

19 MR. WIRMANI: Thank you, Judge.

20 BY MR. WIRMANI:

21 Q. Ms. Brancaccio, before lunch, we were talking about the  
22 training about off-label marketing and kickbacks that you  
23 received at Janssen.

24 Do you recall that?

25 A. Yes.

1 Q. And we looked at an email that looked like it contained,  
2 like, a training module that I believe you testified that you  
3 guys did pursuant to or under the corporate integrity  
4 agreements.

5 Do you remember that?

6 A. Yes.

7 Q. Okay.

8 And just to orient the jury, when we say "corporate  
9 integrity agreement" or "CIA," we are talking about two  
10 different ones.

11 Correct?

12 A. Yes.

13 Q. And those were entered into as a result of settlements  
14 that Janssen and other J&J entities came to with the  
15 Government over allegations of kickbacks and off-label  
16 marketing related to different drugs.

17 MS. BROWN: Objection, Your Honor. Leading.

18 THE COURT: Sustained.

19 BY MR. WIRMANI:

20 Q. And, Ms. Brancaccio, given the presence and the timing of  
21 those corporate integrity agreements, 2010 and 2013, did that  
22 impact your thought process on whether you should go to  
23 Janssen as opposed to the Government with your allegations?

24 A. No. It had no impact.

25 Q. You talked last week about -- or you were questioned last

1 week about -- from Ms. Brown about the Relators' share for  
2 yourself and Ms. Penelow.

3 Do you recall that?

4 A. Yes.

5 Q. And Ms. Brown, I believe she said, You're asking for a  
6 billion dollars.

7 Do you remember that?

8 A. Yes.

9 Q. And I actually think it's 700 million.

10 But suffice it to say, when you first brought these  
11 claims back in 2012, did you have any idea how much money  
12 Janssen would owe back to the Government?

13 A. No, I had no idea.

14 Q. Okay.

15 Did you have to hire experts to even figure that out?

16 A. Yes.

17 Q. When is the first time -- you were here for opening, so I  
18 know you saw it during opening. But before opening, when is  
19 the first time that you saw how much money you were asking in  
20 this case for Janssen to pay back to the Government?

21 A. It was at opening.

22 Q. Okay.

23 A. It was at the opening.

24 Q. We talked last week about the ethics pledge that you  
25 signed, and you were cross-examined about that.

1 Correct?

2 A. Yes.

3 Q. Was there anything ethical about what Janssen was doing  
4 between 2006 and 2014?

5 A. Nothing.

6 Q. Your supervisors, Frank Murphy, Tony Dolisi,  
7 Nancy Bartnett, did they sign similar ethics pledges?

8 A. I'm sure they did.

9 Q. Did everybody at the company sign ethics pledges?

10 A. Yeah, I'm sure they did. Yes.

11 Q. And was pretty much everybody that was involved in the  
12 sale of Prezista and Intelence involved in what you've been  
13 describing to this jury?

14 A. Yes.

15 Q. You were asked about your requests for admission last  
16 week.

17 Do you remember that?

18 A. Yes.

19 Q. And just to orient you -- I know you're not a lawyer --  
20 so it was the -- it was something that you had looked at in  
21 discovery, and you were asked questions, you know, not in  
22 court but before, about that message of low impact on lipids.

23 Do you remember that?

24 A. Yes.

25 Q. Okay.



1 And we've seen the glossy marketing document here in  
2 court. I think they call it a slim-jim?

3 A. Yes.

4 Q. In those admissions, did you ever admit that the FDA  
5 approved that message, or was your admission that Janssen  
6 approved the message?

7 A. It was -- I didn't know if the FDA approved it or didn't  
8 approve it. I assumed that it came from Janssen. I have no  
9 knowledge whether the FDA said this is okay or not okay.

10 Q. Okay.

11 And during the course of your time at Janssen, did you  
12 ever see anything in writing from the FDA that said that that  
13 message, low impact on lipids or low impact on cholesterols,  
14 was acceptable and okay to use in the field?

15 A. No, I never saw anything like that.

16 Q. And you've been a party to this case now for 12 years.

17 Correct?

18 A. Yes.

19 Q. During the course of your time as a party to this case,  
20 have you ever seen a correspondence or document from the FDA  
21 saying that this message, low impact on lipids, was okay to  
22 make in the field about the drug Prezista?

23 A. No, I've never seen anything.

24 Q. All right.

25 Let's -- the last topic I want to talk about, I just

1 want to clear up some issues about this termination.

2 A. Sure.

3 Q. Just so we remind the jury of kind of the timetable here.

4 You received notice, okay, that you were going to be  
5 terminated from Janssen about ten days before we seated this  
6 jury.

7 Correct?

8 A. That's correct.

9 Q. Okay.

10 And Ms. Brown asked you about a meeting with HR.

11 Okay?

12 A. Yes.

13 Q. In that meeting, did you tell HR, I am a whistleblower  
14 and I have a case against Janssen?

15 A. I did.

16 Q. How long has Janssen known that you're a whistleblower?

17 A. Since the case became public in April of 2016.

18 Q. So almost eight years?

19 A. Yes.

20 Q. And Janssen, not through your counsel but through you  
21 personally, brought you that severance agreement and asked you  
22 to sign it.

23 Correct?

24 A. Yes.

25 Q. And your understanding on direct was that that severance

1 agreement required you to waive any rights, any recovery from  
2 Janssen, and all of the claims that you have here in this  
3 case.

4 Is that fair?

5 MS. BROWN: Your Honor, I object. It misstates the  
6 document.

7 MR. WIRMANI: And we're going to look --

8 THE COURT: Hold on. The question was to her  
9 understanding, not what's in the document, so overruled.

10 Continue.

11 MR. WIRMANI: Thank you, Judge.

12 BY MR. WIRMANI:

13 Q. I want to look and gain your understanding of that  
14 document.

15 MR. WIRMANI: So can we bring up what I believe was  
16 Relators' 1704? 1703. And we should have a highlighted  
17 version.

18 BY MR. WIRMANI:

19 Q. And I don't want to dwell on this, but I want to just  
20 take you through this real quick.

21 MR. WIRMANI: Could we go to page 4 of that document.

22 BY MR. WIRMANI:

23 Q. On page 4 of that document, does it say, "By signing this  
24 agreement you release and give up all claims against releasee  
25 of any nature arising under federal, state, local, or foreign

1 law, including, but not limited to, those not mentioned in  
2 this agreement."

3 Do you see that?

4 A. Yes.

5 Q. Okay.

6 And then at the bottom, it says you specifically  
7 "Release any and all claims and rights in any way relating to  
8 or arising out of your employment with any Johnson & Johnson  
9 company or the termination of that employment."

10 And then it says, "except for the excepted rights."

11 Do you see that?

12 A. Yes.

13 Q. And do you recall Ms. Brown asking you if you understood  
14 that excepted rights included your claims here as a  
15 whistleblower?

16 A. Yes.

17 Q. And you -- you honestly answered and said -- and I have  
18 it here.

19 You honestly answered and said, in response to the  
20 question, you know, "One of the things maybe you didn't see is  
21 that whistleblower cases like the one you brought here" --

22 MS. BROWN: Your Honor, I object. Are we just  
23 reading testimony?

24 THE COURT: I'm sorry?

25 MR. WIRMANI: I'm reorienting her to the question.

1 THE COURT: What's the objection?

2 MS. BROWN: To reading testimony from last week.

3 THE COURT: What's the question, Mr. Wirmani? I  
4 can't understand it from what I'm looking at the screen.

5 BY MR. WIRMANI:

6 Q. Last week, Ms. Brancaccio, were you asked by Ms. Brown,  
7 One of the things maybe you didn't see is that whistleblower  
8 cases, like the one you brought here, that's excepted?

9 Do you recall that?

10 A. Yes.

11 THE COURT: I'm okay with that.

12 Overruled.

13 BY MR. WIRMANI:

14 Q. And your answer was "Again, I'm not an attorney."

15 Correct?

16 A. That's correct.

17 Q. Okay.

18 And Ms. Brown made it appear as if excepted included  
19 whistleblower claims. So let's actually look at that.

20 MR. WIRMANI: Can we go to the top of page 3. And  
21 down there at the bottom.

22 BY MR. WIRMANI:

23 Q. And that paragraph there beginning on page 18 beginning  
24 with "except for your right to the" --

25 MR. WIRMANI: Can we go to the next page --

1 BY MR. WIRMANI:

2 Q. -- "payments and benefits provided for in this  
3 agreement."

4 And then it says, "into any vested benefits or  
5 restricted share units, performance share units or stock  
6 options specifically stated to vest before the separation date  
7 or during retirement under the consolidated retirement plan of  
8 Johnson & Johnson, the Johnson & Johnson savings plan or any  
9 retirement savings, incentive or executive compensation plan  
10 in which you participated during your employment."

11 Do you see that?

12 A. Yes.

13 Q. And then does it define there saying, "Collectively,  
14 these things we have just referred to are the excepted  
15 rights"?

16 A. Yes.

17 Q. Do you see anything about whistleblower claims in that  
18 definition of excepted rights?

19 A. No.

20 MR. WIRMANI: Can we go to page 4, please.

21 BY MR. WIRMANI:

22 Q. You see there in green, it says, "You are also releasing  
23 any and all other claims and rights you have against the  
24 releasee," and then again it says, "other than excepted  
25 rights."

1 And we just established excepted rights does not  
2 include whistleblower claims.

3 Correct?

4 A. Yes.

5 Q. Then it goes on to say that "that release includes  
6 whistleblowing."

7 Do you see that?

8 A. Yes.

9 MR. WIRMANI: Can we go to page 4.

10 BY MR. WIRMANI:

11 Q. And we saw this last week. At the bottom of page 4 it  
12 says that you acknowledge and can affirm that you have -- it's  
13 there in blue -- "not filed or caused or permitted to be filed  
14 any pending lawsuit of any type in any form against any  
15 releasee."

16 Do you see that?

17 A. Yes.

18 Q. Is this a pending lawsuit?

19 A. Yes, it is.

20 Q. Could you sign this agreement and get your severance  
21 given this pending lawsuit based on your understanding of that  
22 sentence?

23 A. No, I cannot.

24 Q. And if we look at page 5 down there in orange or yellow,  
25 it says that, "This agreement does waive any right that you

1 have to any monetary award, recovery or settlement from the  
2 company in connection with any such reporting or disclosure."

3 Do you see that?

4 A. Yes.

5 Q. And it says, recovery from the company.

6 A. Yes.

7 Q. And I don't want -- I don't want you to get into what was  
8 discussed, but did you hire a separate lawyer to assist you  
9 with this agreement?

10 A. Yes.

11 Q. And then --

12 MR. WIRMANI: And you can take that down,

13 Ms. Johnson.

14 BY MR. WIRMANI:

15 Q. Then we looked at the back of that agreement, which  
16 contained the names of the 400 employees.

17 Do you recall that?

18 A. Yes.

19 Q. And I believe we established that you were one of -- you  
20 were -- three out of 400 people, including yourself, were not  
21 retained.

22 Correct?

23 A. Yes.

24 Q. Okay.

25 And you understood that to mean, based on your



1 testimony, and correct me if I'm wrong, that you were  
2 terminated and that you had no opportunities to come back and  
3 apply for a job with any of the J&J family of entities?

4 A. That's my understanding.

5 Q. And that was your understanding when you came into court  
6 to start this lawsuit?

7 A. Yes.

8 Q. That was your understanding during opening statement when  
9 Ms. Brown told the jury that I was incorrect and that you were  
10 actually still employed with Johnson & Johnson or Janssen.

11 Correct?

12 A. Yes.

13 Q. And then I believe it was -- it was right after -- if I  
14 remember the date correctly -- right after Sara Strand got  
15 down from the stand, okay --

16 A. Yes.

17 Q. -- you received an email at your work address.

18 Correct?

19 A. Yes.

20 Q. And I believe it was dated May 12th.

21 Correct?

22 A. I think it was May 9th.

23 Q. May 9th. And that was -- was that the first time you had  
24 ever seen that email?

25 A. The first time I saw it was when Ms. Brown brought it up.

1 Q. And what did HR tell you back in April about whether you  
2 should continue to work and do things like access your  
3 computer for work?

4 A. They told me during that phone call that I was to stop  
5 working as of that phone call, no more work.

6 Q. And did Janssen send that same email rehiring you -- let  
7 me stop there.

8 Did that email actually say you were re-hired?

9 A. It said -- yes. It said that I could come back to my  
10 current position.

11 Q. So Janssen changed its mind.

12 Is that how you see things?

13 A. Yes.

14 Q. Was that email also sent to your personal email, to your  
15 knowledge?

16 A. No, it was not.

17 Q. Did you receive a phone call from Janssen saying that you  
18 were re-hired?

19 A. I did not.

20 Q. Did Janssen at all times know that you were here in this  
21 federal courtroom all day not checking your work email?

22 A. I would imagine so, yes.

23 Q. What would have happened if you had signed -- what is  
24 your understanding of what would have happened if you had  
25 signed that severance agreement on April 25th or the 26th or

1 the 27th, the 28th, the 29th, the 30th, May 1st, 2nd, 3rd,  
2 4th, 5th, 6th, 7th or 8th?

3 What is your understanding of what would have happened?

4 A. Then any -- any recovery that I would get from this  
5 trial, this claim, that it would -- I would not be entitled to  
6 it.

7 Q. And then Janssen learns during opening that you're going  
8 to testify, because we said that.

9 Correct?

10 A. Yes.

11 Q. And then before you have an opportunity to take the  
12 stand, they changed their mind, and they say, No, you're  
13 actually still employed.

14 A. Right.

15 Q. And they let that offer, right, to release claims hang  
16 out there for almost two and a half weeks, didn't they?

17 A. Yes, they did.

18 Q. If you had signed that agreement, would this jury have  
19 ever heard your story and what took place at Janssen and had a  
20 chance to rectify that conduct?

21 A. No, they would not.

22 MR. WIRMANI: Nothing further at this time,  
23 Your Honor.

24 THE COURT: All right. Thank you, Mr. Wirmani.

25 Ma'am, you're dismissed at least from the witness box.

1 You can go back to your seat.

2 THE WITNESS: Thank you.

3 THE COURT: Who is next, folks?

4 MR. WIRMANI: Your Honor, Relators call Dr. Aaron  
5 Glatt.

6 THE COURT: Dr. Glatt, I'm going to have you sworn in  
7 before you begin your testimony.

8 (DR. AARON GLATT, HAVING BEEN DULY SWORN/AFFIRMED, TESTIFIED  
9 AS FOLLOWS:)

10 THE DEPUTY COURT CLERK: Please state your name and  
11 the spelling of your last name for the record.

12 THE WITNESS: My name is Aaron Glatt, G-L-A-T-T.

13 THE COURT: You can be seated.

14 MR. WIRMANI: Thank you, Your Honor.

15 (DIRECT EXAMINATION BY MR. WIRMANI:)

16 Q. Dr. Glatt, would you please introduce yourself to the  
17 jury.

18 A. Sure. Hi, my name is Aaron Glatt.

19 Q. And, Mr. Glatt -- or, Dr. Glatt, what is your profession?

20 A. So I'm a physician, an infectious diseases physician.  
21 I'm currently chairman of the department of medicine and chief  
22 of infectious diseases and the hospital epidemiologist at  
23 Mount Sinai South Nassau, which is a tertiary care hospital,  
24 part of the Mount Sinai Health Network in New York.

25 Q. And, sir, how long have you been the chief of medicine,

1 the chief of infectious diseases at that hospital?

2 A. I've been there nine years now.

3 Q. What are your general responsibilities in that role?

4 A. So as chair of medicine, I'm responsible for everything  
5 that goes on within the department of medicine, both from a  
6 quality of care point of view, from policies, procedures,  
7 making sure that we're doing the best thing that we possibly  
8 can for our patients.

9 As chief of infectious diseases, that specifically is  
10 more related to all of the things that we do in taking care of  
11 patients with infectious diseases, to make sure that we're  
12 treating them optimally, to make sure that we're doing the  
13 right thing for them and giving them the best possible care in  
14 a compassionate way as possible.

15 Q. And, Dr. Glatt, do you mind moving the microphone up a  
16 little bit? People have a little trouble hearing you back  
17 here.

18 A. Sure. Is this better?

19 Q. Yes. That's perfect. Thank you.

20 And you mentioned infectious diseases. Is HIV  
21 considered an infectious disease?

22 A. Yes, it is.

23 Q. In your capacity as chief of medicine at this hospital,  
24 do you have the chance to treat and oversee other physicians  
25 treating HIV patients?

1 A. Yes, I do.

2 Q. How long have you been treating the HIV virus, sir?

3 A. So I have been caring for patients with HIV since the  
4 onset of HIV. As a third-year medical student in 1981, we  
5 began seeing this unusual presentation of patients with this  
6 illness, which was subsequently identified as HIV.

7 In my role as a resident, I took care of many patients  
8 with HIV. Certainly as a fellow, I took care of many, many  
9 patients with HIV, and then the rest of my career, I've had  
10 very senior-level experience overseeing the care of thousands  
11 of patients with HIV.

12 Q. You mentioned -- you mentioned like since the inception,  
13 and you talked about you saw this new virus.

14 Explain to the jury what you mean. Were you there on  
15 the ground level when the HIV virus first emerged as a  
16 recognized medical condition?

17 A. Sure. So HIV is a new infection. It wasn't recognized  
18 as being an infection until very early in the 1980s when we  
19 started seeing patients that had this very unusual  
20 presentation of mostly young people getting very serious  
21 infections that they never should have gotten, and it didn't  
22 take very long to figure out what was going on.

23 Their immune systems were being impacted by this virus.  
24 HIV is human immunodeficiency virus. It was a novel virus.  
25 We hadn't seen it before, and one of the most important things

1 that it does is destroys the immune system of the person who  
2 gets infected with it.

3 And we would see these very, very serious  
4 complications, which unfortunately very tragically were almost  
5 always fatal.

6 Q. Dr. Glatt, you said 1983, so if I'm doing my math  
7 correctly, you've been treating HIV patients for almost  
8 40 years.

9 Is that correct?

10 A. Yes.

11 Q. Okay.

12 Just approximately how many patients -- HIV patients do  
13 you think you've treated over the course of your career,  
14 either personally or overseeing others that have done so?

15 A. So as part of my career, I've been the director of two  
16 New York State designated AIDS centers. The first one was  
17 Nassau County, which was called then Nassau County.

18 Now it's Nassau University Medical Center, and we have  
19 thousands of HIV patients that we were taking care of, and I  
20 was the director of that program, overseeing direct patient  
21 care myself as well as all the doctors and physicians in the  
22 program.

23 And then I created, at the Catholic Medical Centers,  
24 which was a four-hospital system in Brooklyn and Queens,  
25 New York, I made them become a New York State designated AIDS

1 center when I was asked to become the chief of infectious  
2 diseases at that system.

3 And we had, again, thousands of patients that we were  
4 taking care of. I was overall responsible for all of them. I  
5 didn't take care of all of them personally, but I was overall  
6 responsible for them and did see a significant percentage of  
7 patients myself.

8 Q. And, Dr. Glatt, at the hospital where you were chief of  
9 medicine, is there an associated medical school?

10 A. Yes.

11 Q. Do you have a role at that medical school?

12 A. Sure.

13 Q. Tell the jury what that is.

14 A. Sure. I'm a full professor at the Icahn School of  
15 Medicine of Mount Sinai. I've been a full professor for over  
16 20 years, first at the Albert Einstein College of Medicine  
17 when my hospital was affiliated with that medical school.

18 Subsequently, when I switched positions, I became a  
19 full professor as well as associate dean at New York Medical  
20 College.

21 And then subsequently, when I switched positions, we  
22 became part of the Mount Sinai system, and I became a full  
23 professor at the Icahn School of Medicine at Mount Sinai.

24 Q. So you've held a number of different teaching posts  
25 throughout your career.



1           Is that fair?

2   A.   Yes.

3   Q.   Just at a high level, what do you teach in the medical  
4   arena?

5   A.   So I obviously have a certain level of expertise in  
6   infectious diseases. I teach a lot of things -- excuse me. I  
7   teach a lot of things in general medicine as well, but my  
8   expertise is specifically in infectious diseases. I have an  
9   interest and teach as well medical ethics to physicians as  
10   well as lay people across the world.

11   Q.   Dr. Glatt, where did you go to medical school?

12   A.   I went to what was then called Columbia University  
13   College of Physicians and Surgeons. That's Columbia  
14   University in New York. It's now called the Vagelos College  
15   of Physicians and Surgeons.

16   Q.   After a medical student goes to medical school, do they  
17   then go on to a residency?

18   A.   Many do. The vast majority do. They select what field  
19   they wish to go into. If they get accepted into that program,  
20   that field, then that's what they train in.

21           I always had an interest in infectious diseases. I  
22   always had an interest in internal medicine, so I first did my  
23   residency -- I actually did an internship residency.

24           And then I was selected to be the chief resident. I  
25   was the only one in my group that was selected to be that

1 chief resident for three years at what then was called the  
2 Brookdale Hospital Medical Center, subsequently became the  
3 Brookdale University Medical Center.

4 Then I chose to do an infectious disease fellowship at  
5 the State University of Downstate Health Science Center,  
6 which, in my opinion, then was the premier and still is today  
7 one of the premier infectious disease training places in the  
8 United States.

9 So it's one of the largest programs, and we saw a  
10 breadth of illness that many, many hospitals didn't see.

11 Q. And, Dr. Glatt, you mentioned most medical students do  
12 residencies, but you also mentioned a fellowship.

13 What is a fellowship?

14 A. So a fellowship is additional training that an  
15 internist -- when I finished my internal medicine residency, I  
16 became an internist, which is basically a doctor for adults.  
17 There's also pediatrician, a doctor for children. So we are  
18 the doctors for adults.

19 And that's a general field of internal medicine. It  
20 takes care of all different parts of the body: heart, lungs,  
21 kidneys, infections, too.

22 But then I chose to do an additional two years of  
23 training to become even more of an expert in infectious  
24 diseases, and I became board certified both in internal  
25 medicine and infectious diseases.

1 Q. And fair to assume that, during the course of the  
2 residencies and the fellowships, you spent time learning about  
3 and treating patients with HIV?

4 A. Yes, I did.

5 Q. Have you won any awards related to infectious diseases  
6 and the treatment of HIV?

7 A. Yes, I have.

8 Q. What are those awards, Doctor?

9 A. So there are a number of awards that I've won. I most  
10 recently received from the New York State American College of  
11 Physicians their laureate award, which they award to a  
12 handful, one or two three per year, for being an outstanding  
13 physician in New York State. I was very honored to get that,  
14 and that was in 2020.

15 At the same time, the American College of Physicians,  
16 which is the major internal medicine society encompassing  
17 probably over a hundred thousand physicians, awarded me its  
18 highest accolade, which is to become a master of the American  
19 College of Physicians.

20 I previously had been fellow, which is a high accolade,  
21 after having been a member. A handful of people across the  
22 world each year are selected to be a master of the American  
23 College of Physicians, and in 2020, I was selected to be a  
24 master of the American College of Physicians.

25 Q. Dr. Glatt, as a -- as a master within that organization,

1 is that the highest level that a physician can obtained?

2 A. Yes, it is. There's probably less than -- well, less  
3 than 1 percent of the physicians in the world that have  
4 attained that status.

5 Q. And I don't want you to go through job by job, but just  
6 outside of your current position at the hospital, what other  
7 significant work experience do you have treating HIV patients?

8 A. Throughout my career, I've either directly taken care of  
9 or have overseen the care of patients with HIV infection.

10 I have -- as part of my responsibilities, I've been the  
11 chair of the pharmaceutical and therapeutics committee, which  
12 deals very much with what medications are going to be used in  
13 the hospital and what's the appropriate usage of them.

14 I was selected to be the person in charge of an  
15 eight-hospital system to do that. I currently serve a similar  
16 role at my current hospital.

17 I've done numerous -- thousands of talks in my career,  
18 both at my hospital as well as the system hospitals that I've  
19 been invited to, grand rounds at various hospitals across the  
20 United States.

21 I've lectured internationally on this. I was invited  
22 by the Russian Government to actually present on HIV infection  
23 to the Russian Government back in the pre-Putin era.

24 Q. Dr. Glatt, what is an academic journal?

25 A. So I don't know if there's an exact scientific definition

1 of academic journal. There are many journals that are  
2 considered to be really the top places for a person to go and  
3 try to get their research published in.

4 Top flight journals would include a number of different  
5 journals, both in general internal medicine and infectious  
6 diseases, from my perspective, but they're available in every  
7 other subspecialty as well.

8 Q. And have you published articles that have appeared in  
9 these academic journals?

10 A. Yes, I have.

11 Q. Approximately how many have you published?

12 A. So I published over 140, 150 articles, not all of them in  
13 the top flight journals. One of my first publications,  
14 however, was in the New England Journal of Medicine, which is,  
15 again, arguably one of the most premier medical journals.

16 It was the first paper published on the treatment of  
17 HIV opportunistic infections, and I published that in 1988.

18 Q. And do practitioners that are treating HIV patients, do  
19 they look to these academic journals and the research there in  
20 terms of gaining more insight and experience with the disease  
21 state?

22 A. I certainly would hope so. They certainly do. That's  
23 how you keep abreast of the current literature. When you  
24 finish your residency, you need to maintain. I consider  
25 myself still a student of medicine. You need to constantly

1 learn and constantly be kept abreast of what's going on.

2 Q. These journals that you've published articles in and that  
3 doctors look to, do they have a review process, like peer  
4 review and editors, that -- that vet the information to make  
5 sure that it is as accurate and precise as possible?

6 A. Sure. So all the top journals have a very rigorous  
7 peer-review process whereby people who are unaffiliated with  
8 your research and usually unaffiliated with you and/or your  
9 institution review your paper that you submitted, critique it,  
10 point out the flaws or the good things in it and, again, goes  
11 to the editorial board or to an editor of the journal to then  
12 make a decision, Do we wish to pursue this publication in our  
13 journal further or do we wish to just reject, maybe give them  
14 a critique, or do we wish them to resubmit it with the  
15 critique that we've outlined and that they have an opportunity  
16 to make appropriate changes in the article to address the  
17 concerns that have been raised.

18 Q. And, Doctor, in addition to publishing articles, have you  
19 served in these review capacities where you're either  
20 peer-reviewing other people's articles or serve in an  
21 editorial capacity?

22 A. Yes, I have.

23 Q. Approximately how many times have you done that?

24 A. I don't have a way to count that; many, many times. I've  
25 served on the editorial boards of various journals. I have

1 reviewed numerous articles in a peer-review capacity in that  
2 respect.

3 It takes a tremendous amount of time. It's all  
4 volunteer time, and I have enjoyed doing it, but it does take  
5 a tremendous amount of time to do it right.

6 Q. Have you also published books or chapter of books or  
7 textbooks related to infectious diseases and HIV?

8 A. Yes, I have. One of the major publications that I did  
9 was for what's a series of publications called the *Infectious*  
10 *Diseases Clinics of North America*, which is a major  
11 publication.

12 I was asked to be the editor of their HIV clinics, as  
13 it's called, and I had to recruit experts from across the  
14 country to go and write various chapters on that, and I wrote,  
15 with some coauthors, two of those chapters myself, and that  
16 was a major publication that we did.

17 In addition, I've written in a number of different  
18 books, chapters in those textbooks, medicine textbooks on HIV,  
19 different aspects of HIV infection.

20 Q. And have you received grants from either the private  
21 sector or the Government to do research related to HIV and  
22 AIDS?

23 A. Yes, I have.

24 Q. And just a brief overview of kind of the research -- the  
25 types of research you've done.

1 A. Sure. So I've done a decent amount of research for the  
2 care and treatment of patients with HIV through what's called  
3 the AIDS Clinical Trials Group, that's ACTG, and that is a  
4 Government-funded multicenter, multistate process whereby we  
5 do studies to identify what are the best agents to treat  
6 different aspects of HIV infection.

7 And in one of the institutions, I was the principal  
8 investigator for all of our ACTG studies. We participated in  
9 a number of different studies. I've received grants from both  
10 the New York State Department of Health and other Government  
11 agencies to do various work on specific complications of HIV,  
12 specific infections the patients with HIV are unfortunately  
13 highly likely to get.

14 And then I have done some additional research, which  
15 may be funded from different agencies.

16 Q. And you mentioned -- you mentioned the Government. Have  
17 you also served on Government committees and society  
18 committees addressing particular infectious disease issues?

19 A. Yes, many times.

20 Q. Okay.

21 Are there any that are particularly relevant to your  
22 expertise in HIV and AIDS?

23 A. Sure. So I've served on the major infectious disease  
24 society, the Infectious Diseases Society of America, as well  
25 as the major epidemiology society, the Society of Hospital



1 Epidemiologists of America. I've served -- still serve in  
2 some capacities in both of those organizations.

3 I've served on their education committees. One of the  
4 most important things that we do is educate physicians about  
5 all sorts of infectious diseases, including HIV.

6 I've served on various panels from both the federal  
7 government as well as from the state and have served on many  
8 regional panels and very many society panels in regards to  
9 both infectious diseases and specifically in regards to HIV  
10 infection.

11 Q. And I think you mentioned earlier that you've given  
12 thousands of lectures.

13 Have some of those lectures or a significant portion of  
14 those lectures dealt with the issues of infectious diseases  
15 and HIV?

16 A. Yes.

17 Q. What types of places do you go speak?

18 A. So I essentially only speak in hospital settings. I'm an  
19 invited speaker at various hospitals. I'm invited to speak,  
20 for example, next week in a major Boston hospital to give them  
21 a special talk on medical ethics, actually.

22 I speak when I've been invited at various hospitals  
23 across the country, even across the world, to give talks on  
24 various infectious diseases, including HIV.

25 I speak mostly, obviously, in my own hospital. I train

1 residents. I train fellows. I've been a program director of  
2 a fellowship for many years. And in my roles as chief of  
3 infectious diseases, chair of medicine, chief medical officer,  
4 and even as the president of a hospital, I've always given  
5 lectures. I find that one of the most, you know, personally  
6 satisfying aspects of my job, to train and teach young  
7 doctors, as well as older doctors, as much as I possibly can.

8 I enjoy that very much, and I think it's very helpful.  
9 I can impact many, many lives, hopefully, that way.

10 Q. So it sounds like these speeches that you give, typically  
11 your audience is other physicians that you are teaching.

12 Is that fair?

13 A. Well, I actually give a lot of lay lectures as well. But  
14 my professional goal, really, is really more to educate the  
15 professional audiences. But with COVID, especially, I've  
16 given numerous, numerous talks to the lay public as well.

17 Q. Okay.

18 And besides your current -- your current medical  
19 school, have you served on the committees of other medical  
20 schools in the past?

21 A. Yes, I have.

22 Q. Just briefly describe some of the committees you've  
23 served on.

24 A. So I've been on the Stony Brook senate. I've been on the  
25 pharmacy and therapeutics committee or have chaired the

1 pharmacy and therapeutics committee at every hospital I've  
2 ever been on.

3 I have been the chief of infectious diseases or the  
4 hospital epidemiologist at every hospital I've ever been at.

5 I've been chair of the department of medicine at my  
6 current hospital and at a previous as well.

7 I have been a chief medical officer as well.

8 Q. In your practice as an HIV practitioner, have you heard  
9 the term "an HIV thought leader"?

10 A. Yes, I have.

11 Q. I think the jury's heard that term kind of thrown around  
12 here. Can you tell the jury: What are the types of things  
13 that you would expect to see an HIV thought leader do?

14 A. So I don't think there's a technical definition for that.  
15 My definition for that would be somebody that people look to  
16 for advice, expertise, suggestions as to how to best manage  
17 patients.

18 They are the people that may have more experience than  
19 you. They may be the people that have actually done some of  
20 studies themselves, and you want to hear about the actual  
21 studies more than maybe has been published in the literature.  
22 They're the people that often put together policies and  
23 guidelines for the care of those patients.

24 They're the people that you look up to in your field to  
25 give you guidance when you need help.

1 Q. And, Dr. Glatt, I'm not going to ask you if you consider  
2 yourself to be a thought leader, but have you done many of the  
3 types of things that are typically associated with HIV thought  
4 leaders?

5 A. I have done a lot of things I just said, yes.

6 Q. I want to shift now to some of your opinions, but let me  
7 start with this: Have you personally prescribed or overseen  
8 others prescribing the Janssen drugs Prezista and Intelence?

9 A. Yes, I have.

10 Q. And you -- your understanding, correct, is you are  
11 testifying in this courtroom as an expert witness.

12 Is that fair?

13 A. Yes.

14 Q. Tell the jury: What is the area of your expertise?

15 A. So I'm a board-certified infectious diseases physician.  
16 I have done both my own original research plus I have reviewed  
17 many published studies. I teach. I'm a full professor of  
18 medicine. And I care for many, many patients and have  
19 overseen thousands of patients with HIV infection, if that  
20 answers your question.

21 Q. Yes. And when were you first retained by the Relators in  
22 this case?

23 A. I don't remember the exact date, but it would have been  
24 probably some time in 2017, 2018.

25 Q. Okay.

1           What is your hourly compensation rate?

2   A.   My hourly current -- currently it's \$800 per hour.

3   Q.   Okay.

4           And when you were retained in this case, what -- just  
5   in your own words, what were you asked to do?

6   A.   So my recollection of the conversation was I was asked to  
7   go and evaluate some of the claims that were being made, and  
8   as always, I say, I don't do this very often. But whenever  
9   I'm asked to evaluate cases in the hospital, I say, I will  
10   evaluate them independently and I'll come to my own  
11   conclusions, which is what I did in this case as well.

12   Q.   And when you say you were asked to evaluate various  
13   claims, are those the alleged off-label marketing claims, the  
14   illegal off-label marketing claims involving the drugs  
15   Prezista and Intelence?

16   A.   Yes. Amongst other things, yes.

17   Q.   Okay.

18           And is it your understanding that those claims are that  
19   Prezista is safe and effective for treatment-naive patients  
20   between the years 2006 and 2008?

21   A.   Yes.

22   Q.   Is it your understanding that one of the claims is that  
23   Prezista is lipid neutral or lipid friendly or has a similar  
24   impact on lipids as Reyataz?

25   A.   I was asked to evaluate that, yes.

1 Q. Okay.

2 And on the Intelence side, were you asking to evaluate  
3 the claim that Intelence is appropriate, safe, and effective  
4 for treatment-naive patients?

5 A. Yes.

6 Q. And on the Intelence side, were you asked to evaluate the  
7 marketing message that Intelence is safe and effective for  
8 once-daily dosing, or to be taken only once a day as opposed  
9 to twice?

10 A. Yes.

11 Q. Were you also asked to review some Janssen speaker slide  
12 decks?

13 A. Yes, I was.

14 Q. In formulating your opinions, what materials did you  
15 review? I know you don't remember them all, but just  
16 generally tell the jury.

17 A. So I, obviously, reviewed the four items, plus the  
18 speaker's programs information that was provided to me. I was  
19 provided -- I don't have independent knowledge, but I was  
20 provided with the statements that their Relators made in  
21 regards to the case.

22 I was provided with the slide decks that were being  
23 used by -- the slide decks for both marketing Prezista and for  
24 Intelence. I was provided ultimately with additional  
25 documents that I reviewed.

1 Q. Okay.

2 In preparation for your testimony today, did you assist  
3 and get feedback in creating some slides to kind of guide the  
4 jury through your opinions?

5 A. Yes, I did.

6 Q. Do you believe that those -- that that slide deck will be  
7 helpful to this jury in understanding your expertise and your  
8 expert opinions?

9 A. I think so. When I lecture, I almost always use slides  
10 when I lecture. It makes it, I think -- the points very  
11 clear, and I can expand upon them and can take questions upon  
12 them. I don't assume the jury will be asking me questions,  
13 but when I give lectures to people, we take questions all the  
14 time, and we can expand upon something if it's not clear.

15 Q. Okay.

16 MR. WIRMANI: And, Your Honor, I'd move to admit for  
17 demonstrative purposes what will be Relators' 1706? 1709.

18 MS. BROWN: I haven't seen it, Your Honor. Could I  
19 have a copy, please.

20 THE COURT: Yes.

21 MS. BROWN: Your Honor, it's fairly lengthy. I don't  
22 want to hold this up. If we want to go slide by slide, I'll  
23 review it and let the Court know if I have an objection.

24 I have no objection as a demonstrative, but I do as  
25 admission.

1 THE COURT: Yeah. Is it demonstrative, or are you  
2 trying to move to admit it?

3 MR. WIRMANI: It's demonstrative only, Judge.

4 THE COURT: All right. So then let's continue to  
5 move forward.

6 MS. BROWN: Thank you, Your Honor.

7 BY MR. WIRMANI:

8 Q. Dr. Glatt, starting with the Prezista marketing claims,  
9 what ultimate opinions did you reach?

10 A. So the opinions that I was asked to reach were based upon  
11 the label for Prezista, which was approved in 2006, and then  
12 the label that was changed in 2008 to see whether those  
13 labels, which is how a pharmaceutical industry is supposed to  
14 market their drug, were adhered to or not.

15 Q. And with respect to the claim that Prezista was safe and  
16 effective for treatment-naive patients between 2006 and 2008,  
17 did you find that to be inconsistent with the label?

18 A. Yes.

19 Q. Did you find it inconsistent with clinically appropriate  
20 standards of care for HIV patients during that time period?

21 A. Based upon the guidelines that were available at that  
22 time, it was not recommended for that group of patients.

23 Q. Okay.

24 And with respect to claims that Prezista was lipid  
25 neutral, lipid friendly like Reyataz, did you find that to be



1 inconsistent with the label for Prezista?

2 A. I find that to be wrong. I find that to be absolutely  
3 not consistent.

4 Q. And when you say "wrong," do you mean that you found it  
5 to be false?

6 A. Correct.

7 Q. Okay.

8 And what about under the appropriate standard of care  
9 for HIV patients during the time period of 2006 to 2014?

10 Would that representation be inconsistent with the appropriate  
11 standard of care?

12 A. Please repeat the question. Between 2006 and 2008?

13 Q. 2006 and 2014 for Prezista --

14 A. Okay. So for the lipid --

15 Q. -- for the lipid claims.

16 A. For the lipid claims, it would be inappropriate for the  
17 entire period of time.

18 Q. Okay.

19 Under the standard of care in the profession for HIV  
20 patients.

21 A. Correct.

22 Q. And with respect to Intelence, did you reach the  
23 conclusion that the marketing message that Intelence is  
24 appropriate for treatment-naïve patients between 2006 and  
25 2014, that this was inconsistent with the label?

1 A. It is inconsistent with the label.

2 Q. Okay.

3 Do you also find that that marketing message was  
4 unsupported and inconsistent with the appropriate standard of  
5 care for HIV patients during that time period?

6 A. Yes. In fact, the guidelines specifically stress do not  
7 use it for that indication.

8 Q. And then with respect to the claim that Intelence can be  
9 taken once a day, what were your conclusions with respect to  
10 that marketing claim?

11 A. So there is no current recommendation to give this drug  
12 once a day. The drug, in every legitimate repository of  
13 information, says that it should be given twice daily.

14 Q. Okay.

15 And, obviously, you've mentioned the label. We're  
16 going to talk a little bit more about kind of the medical  
17 guidelines you've relied on in formulating your opinions.

18 With respect to the speaker program and those slide  
19 decks, what ultimate opinion did you reach?

20 A. So I reviewed the slide decks in detail. There were  
21 many, many different slide decks that I reviewed. With the  
22 exception of the change in the label from 2006 to 2008 for  
23 Prezista, the material was extremely duplicative. It didn't  
24 add any information. The attendees were very small in number.

25 Astonishingly, many of the attendees themselves were

1 speakers on the same slides. I can't understand how anybody  
2 would be able to sit through that on a regular basis and sit  
3 through the same slides that they had themselves given a  
4 lecture on. And I can't understand any educational value in  
5 that, for a person to hear the same slide set over and over  
6 again, sometimes as a speaker, sometimes as an attendee,  
7 unless they were being compensated for it.

8 Q. Okay.

9 And assuming that those were the actual slide decks and  
10 there was nothing more presented at those speaker programs,  
11 what is your ultimate opinion as to the educational value of  
12 those programs?

13 A. I think that probably -- and a single listening to them  
14 would be more than adequate. Again, if there was a change in  
15 the label, maybe a second time to hear it might be  
16 appropriate.

17 Again, I don't see any educational value to constant  
18 repetition of the same lecture over and over again given to  
19 people who have given that very lecture itself.

20 Q. Okay.

21 And just so the jury has an understanding, in terms of  
22 the facts of this case, were you provided those materials by  
23 Relators and asked to assume the truth of them?

24 A. Correct. I have no independent knowledge of any of that.

25 Q. Okay.

1           So your expertise is looking at the facts as alleged  
2 and providing this jury guidance in terms of, if those facts  
3 are true, what your conclusions are.

4           Is that fair?

5 A.   Correct. I never went to a single one of those lectures,  
6 and I never gave any of those lectures.

7 Q.   What is HIV?

8 A.   So HIV, as I mentioned, is a virus known as human  
9 immunodeficiency virus. It was first recognized and named in,  
10 I think, 1985. It had several earlier names. Ultimately,  
11 this was the name that was decided upon to be used.

12           It was a new virus. We hadn't seen it previously, and  
13 its major impact, unfortunately, is to destroy the human  
14 immune system, which protects your body from getting various  
15 infections.

16           Unfortunately, and very tragically, it will kill the  
17 vast majority, probably 95 to 98 percent, of the people that  
18 got HIV who don't get treatment for the underlying viral  
19 infection. And we, unfortunately, saw many, many, many  
20 patients die during that first decade of HIV. It was  
21 extremely sad. It was extremely difficult. We had no  
22 effective therapy to prevent the continuing destruction of  
23 their immune system.

24           What we would do is we would treat some of the  
25 infections that they would get with a modicum of success, but

1 ultimately, with the exception of a small percentage of  
2 patients that we still don't understand why they didn't  
3 progress, 95 to 98 percent of those patients progressed and  
4 died.

5 Q. Dr. Glatt, how is the HIV virus spread?

6 A. So it can be spread in a number of ways. Pardon the --  
7 I'm using technical terms. Pardon if I'm insulting anybody.  
8 It can be spread sexually. It can be spread via contact  
9 between one person and their partner, whatever gender they may  
10 be, through what we would normally call heterosexual  
11 intercourse or through nonheterosexual intercourse. It can be  
12 spread by the sharing of semen from one person to another  
13 person. It can be shared sometimes through blood exchange or  
14 sometimes through other secretions from the body that contain  
15 virus in it.

16 That's probably the -- one of the most important ways.

17 Another very, very important way is through direct  
18 contact with blood from a person who's infected with HIV.  
19 HIV, unless you're being treated, will have high  
20 concentrations of the virus in your blood. And if you were  
21 unfortunate in the 1980s, for example, to need -- to undergo  
22 heart surgery and need heart surgery, where you get many, many  
23 units of blood -- so healthy young people, who previously were  
24 healthy and young, were often donors, and they may have been  
25 infected silently with HIV initially, and the blood supply

1 was, for lack of a better term, contaminated. And many people  
2 who underwent surgery, unfortunately, became sick from HIV  
3 from their surgery.

4 In addition, if you were a substance abuser, if you  
5 used drugs, intravenous drugs, and you would share needles.  
6 So a person who put the needle inside their own body and then  
7 gave the needle to a friend to use, so that would potentially  
8 transmit from their own body into the other person.

9 And those were the main roots of HIV transmission.

10 It's unfortunate and tragic. You can also get it by  
11 being a physician or a nurse if you get a needle stick or if  
12 you get an exposure from a patient in a hospital.

13 Q. Thank you, Dr. Glatt.

14 We've all heard the term "HIV," but we've also heard  
15 AIDS. So can you explain to the jury: What is the difference  
16 between HIV and AIDS?

17 A. Okay. So HIV, as I mentioned, is the virus that destroys  
18 the human immune system. When it destroys it enough, you get  
19 a clinical syndrome, meaning clinical illness, that's known as  
20 AIDS. There were certain infections that, by definition, when  
21 you got them, you now went from just having, quote HIV  
22 infection to now having AIDS.

23 The way I used to teach it was HIV then was a one-way  
24 street and there was a cliff at the end. And you started off,  
25 when you got the original HIV infection, at this end of the

1 street. And as time went on, it would destroy your immune  
2 system. You would be going down the street, down the street,  
3 getting complications down the street, down the street until,  
4 unfortunately, actually, you fell off the cliff and died.

5 We could, for a limited period of time, treat some of  
6 those infections, but eventually, because we weren't treating  
7 the underlying HIV, the patient would succumb.

8 With the advent of what we call antiretroviral therapy,  
9 ART -- you may have seen that originally we called it highly  
10 active antiretroviral therapy -- I had actually coined the  
11 term "highly effective antiretroviral therapy," HERT, but the  
12 HAART took over and became the accepted term, and then ART  
13 became the accepted term.

14 So for the first time, we were able to reverse the  
15 patients going down that one-way street, and we were able to  
16 -- I wouldn't say the word "cure," but with the advent of  
17 better and better and better agents over time, we were able to  
18 stop that immunosuppression, reverse it, and to the point  
19 where patients with HIV infection today, and even years ago,  
20 were living almost normal life spans in terms of expected life  
21 spans as long as they were taking their medication and as long  
22 as those medications were successful and effective.

23 And this was, you know, a huge, huge advance.

24 Q. And, Dr. Glatt, you mentioned kind of, you know,  
25 antiretrovirals and how that has changed the prognosis for

1 these patients and how they're treated. Can you just explain  
2 to the jury: How do these drugs treat the virus, and then  
3 what are some of the challenges in using these drugs?

4 A. Sure.

5 So the first antiretroviral virus, HIV -- I may not  
6 have mentioned this. I said it's a virus. It's actually a  
7 retrovirus. That's the name of a certain type of virus class.  
8 And when the first drug became available in 1987, the drug  
9 known as AZT, it was really revolutionary in that we now had a  
10 drug that could actually treat the underlying cause of their  
11 illness.

12 Unfortunately, we very quickly realized that it was  
13 only a temporary solution and that because of the mutations  
14 that the virus would have, it would invariably develop  
15 resistance to AZT. And when other those drugs were developed,  
16 so we tried those drugs, and it would invariably develop a  
17 resistance to them, until we finally realized that by  
18 combining drugs -- people like to use the term "cocktail."  
19 We'd combine different drugs. And first we had one class of  
20 drugs -- I'll use the vernacular term, the nukes because they  
21 were NRTIs -- I won't get very technical unless I'm requested  
22 to -- but that class of drugs, a number of drugs in that class  
23 came out, and then we started to combine those drugs, and they  
24 were more effective than they were used alone.

25 And then new classes of drugs came out: First the PI



1 class, the protease inhibitor class, and almost simultaneously  
2 what we call the non-nukes, the NNRTIs. And those were the  
3 three major classes of drugs that we had during this relevant  
4 period of time. And we learned over time how to better use  
5 these drugs, how to combine them, which combinations were most  
6 effective, which combinations would be preferred -- sometimes  
7 they wouldn't be as preferred but needed to be used when you  
8 couldn't take the more preferred regimen -- which regimens you  
9 wanted to keep in the back pocket so you could use them in  
10 case resistance developed, because that was what we were  
11 always fighting.

12 And then at the same time, we were trying to make sure  
13 that we would give regimens patients could take. It was very  
14 difficult for patients to take some of these regimens, which  
15 involved many, many pills many times during the day.

16 Q. And, Dr. Glatt, you mentioned kind of this challenge of  
17 resistance, and then I believe you said when this develops,  
18 then they have to be changed to another cocktail of drugs.

19 Is that fair?

20 A. Correct.

21 Q. Okay.

22 And you also said that during this time period, 2006 to  
23 2014, a lot of these HIV patients were living largely normal  
24 lives. So was there still a chance of running out of drugs  
25 during that time period?

1 A. Absolutely.

2 The drugs were much better, but certainly nowhere near  
3 perfect. The drugs we have today are much better than the  
4 drugs we had then. They're still not perfect. And HIV is  
5 constantly mutating. It's constantly changing.

6 We are doing better as well. We're developing newer  
7 drugs; we're developing better ways to give these drugs. And  
8 around the time of the relevant period of time, patients were  
9 starting to live much longer. And during this change in the  
10 way we were treating patients, we realized that it was much  
11 more important now to think of long-term consequences.

12 In the middle to late 80s, we weren't concerned with  
13 what would happen 20 years later with heart disease. They  
14 didn't live 20 years later to get heart disease. And this  
15 28-year-old person in front of you would not, unfortunately,  
16 live long enough to get heart disease.

17 Once we started having much better treatment regimens,  
18 so then patients would start living longer. And the actuarial  
19 tables would show that they would live almost a normal life  
20 span. And then you really needed to take into consideration  
21 the impact that your treatments, as well as the underlying  
22 HIV, would have on naturally occurring as well as artificially  
23 occurring conditions that you were creating and try to manage  
24 the patients so that they not only would not die from their  
25 HIV, but they wouldn't die from a heart disease or stroke or

1 something else.

2 Q. And, Dr. Glatt, let me stop you there. And we're going  
3 to come back to this issue of kind of the relevant time period  
4 and the other challenges that these HIV patients started to  
5 face.

6 But I want to start just by orienting the jury with  
7 some terminology that you used in the treatment of HIV and  
8 AIDS.

9 So we've heard during this case the terms  
10 "treatment-naive" and "treatment-experienced." Can you, in an  
11 understandable way, just explain to the jury what those two  
12 categories are?

13 A. Sure.

14 So in a nutshell, make it really simple, a naive  
15 patient is someone who has never been treated for the HIV  
16 virus itself. They may have been treated for a complication  
17 of HIV, but they haven't been treated for the virus itself.  
18 That's what we call a naive patient.

19 A treatment-experienced patient is someone who has  
20 specifically been given an antiretroviral therapy, ART; they  
21 have been specifically given that type of a therapy.

22 And the difference between the two is the likelihood of  
23 having developed resistance and the likelihood of having  
24 certain complications.

25 Q. Dr. Glatt, is -- you mentioned earlier mutations. Is

1 that one of the ways that a patient -- in fact, one of the  
2 principal ways a patient would go from the naive bucket to the  
3 experienced bucket?

4 A. Well, by giving people therapy, it selects or pushes  
5 certain types of genetic mutations in the virus. It will  
6 occur naturally as well, but by giving them certain therapies,  
7 you're selecting out sometimes resistant strains.

8 When we're only giving one drug, if a resistant strain  
9 developed, that was it. That drug was no longer good.

10 When you're giving two, three, four drugs -- so now  
11 you're hoping that, even if it becomes resistant to, let's  
12 say, Drug Number 1, Drugs Number 2, 3 and 4 or sometimes even  
13 more would still kill it off and that you would not generate  
14 strains that would be resistant to all of those drugs.

15 And that's the idea behind the cocktail behind a  
16 combination therapy of drugs. Even with that, it sometimes  
17 didn't work, and they would develop resistance to all of the  
18 drugs that they were on.

19 Q. Dr. Glatt, what is the concept of adherence or -- in  
20 easier to understand terms, just the idea that HIV patients  
21 need to take their pills?

22 A. Sure. So "adherence" means exactly like the word sounds,  
23 how closely they adhere to taking what they're supposed to be  
24 taking.

25 This is very, very important because, when you're

1 taking these medications, you want to make sure that around  
2 the clock, 24/7, the patient has enough drug in their body  
3 still that will be able to fight off any virus that's present.

4 If you leave them with some drugs that you have an  
5 adequate concentration in the blood but other drugs that you  
6 don't, it's like you're giving them a single drug at that  
7 point in time, and they can develop a resistance much more  
8 easily.

9 So what you try to do is to make sure that with all the  
10 drugs that you're giving them, they have a constant level of  
11 all of the drugs at all times, and not all them have the same  
12 dosing regimen, so that made it very complicated.

13 And, in addition, you want to make sure that they take  
14 it, so clearly it became known -- I don't think anybody would  
15 argue with this -- the less frequently each day you have to  
16 take pills and the less pills that you have to take each day,  
17 that would enhance compliance. That would enhance patients  
18 being able to take the right medicine that they were being  
19 prescribed.

20 The guidelines certainly recognized that. I can't  
21 imagine anybody in the country disagreeing with what I just  
22 said. It's so basic and fundamental from a common sense point  
23 of view, but there are studies that demonstrate that this is  
24 true.

25 And just think about it yourself. If you're asked to

1 take a pill once a day -- one pill once a day, what's the  
2 likelihood if you're doing that, than if you're asked to take  
3 six pills three times a day, you take this one; and two times  
4 a day, you take this one; and four times a day, you take this  
5 one, you know, the pill boxes are huge.

6 One pill once a day, that would be an ideal goal,  
7 not -- not always able to do that, but that was a goal, and  
8 everybody tried to do that. All the different pharmaceutical  
9 companies tried to develop ways they could combine the drugs  
10 into one pill and ideally once a day.

11 Q. Dr. Glatt, that kind of brings us to our next topic. So  
12 you said that adherence is -- you know, you've got to take  
13 your pills, and I understand from your testimony, if you don't  
14 take your pills, you might develop resistance and then have to  
15 go to new drugs.

16 So you talked about dosing convenience, and I believe  
17 you told the jury that, you know, there are studies, and it's  
18 common sense that, you know, less pills is going to be more  
19 attractive.

20 Based on your experience, do doctors and patients have  
21 a strong preference for HIV antiretroviral that can be dosed  
22 once a day as opposed to two or three or four times a day?

23 A. Absolutely.

24 Q. And is that been kind of your universal experience in the  
25 profession since that type of drug has been on the market?

1 A. Certainly it's been my experience. I think it's been  
2 everybody's experience. The guidelines recommend that. All  
3 the pharmaceutical industry tried to come up with combinations  
4 of drugs that can be taken less frequently and to make them  
5 into a single pill.

6 Even though you could take all three in, let's say,  
7 separate pills, it's just much easier, from a compliance point  
8 of view, for the patient's ease and number of pills you have  
9 to take -- a lot of these patients had difficulty swallowing.  
10 They had various medical conditions that made swallowing  
11 sometimes painful. Some of these are horse pills. Some of  
12 these are big pills.

13 And the more pills you're asking the patient to take  
14 the more times a day, just the more likely that they're not  
15 going to be as compliant as you would like.

16 I think that's -- I can't imagine anybody disagreeing  
17 with that.

18 Q. Okay.

19 And the idea of adherence and resistance, that's also  
20 related to a concept called "sequencing."

21 Correct?

22 A. Correct.

23 Q. Tell the jury what sequencing is and how it comes into  
24 play in the treatment of an HIV patient.

25 A. So the sequencing that I'm referring to now is that we

1 want to make sure that we treat as optimally as possible the  
2 patient in front of us right now in whatever year, time it is  
3 but not necessarily to leave nothing behind, nothing in your  
4 back pocket that you could treat them when they develop  
5 resistance.

6           During this period of time, the expectation was that  
7 almost all of the patients would eventually develop  
8 resistance, and if you gave them a combination of drugs, that  
9 if they became resistant to that, you'd have nothing left.  
10 That's not a good thing.

11           In all of the guidelines -- all the guidelines clearly  
12 state, well, this is the preferred agent and why. This is the  
13 alternative agent when you can't take that preferred agent and  
14 why.

15           These are agents that you specifically -- the  
16 guidelines say specifically, do not use this agent right now  
17 because we want to save it for later on. You know, it's  
18 somewhat of a paradox.

19           Sometimes the agent that they will tell you not to use  
20 is a good agent, but they're telling you, Don't use it now, to  
21 save it, because that patient right now doesn't need it, and  
22 you want to save it for when they will need it.

23           And those are all consensus guidelines by the biggest  
24 experts in the field, and not only in one guideline, in the  
25 two major guidelines, which were written by different people,



1 but almost were identical, essentially, in their instructions  
2 of recommending patients for physicians across the country.

3 Q. So, Dr. Glatt, it sounds like what you're saying is you  
4 want to preserve as many different treatment options for these  
5 patients as possible and that there are some HIV medications  
6 that are better to be given early and some that are better to  
7 save because they are more resistant to mutations.

8 Is that fair?

9 A. Absolutely. I can't imagine anybody disagreeing with  
10 that because that's what the consensus guidelines state, and  
11 it's based upon scientific evidence.

12 Q. You talked about this period where HIV patients are  
13 living longer and other health conditions that these patients  
14 started to become far more relevant in treating physicians.

15 In that context, are lipids and cholesterol -- is that  
16 a particular concern for HIV patients?

17 A. Absolutely.

18 Q. Tell the jury why.

19 A. So for a number of reasons. HIV in and of itself doesn't  
20 only impact the immune system. I described to you previously  
21 how it destroys the immune system. It has many impacts on the  
22 rest of the body.

23 One of the things HIV in and of itself can do is cause  
24 problems with your lipids, your triglycerides and your  
25 cholesterol and especially the bad cholesterol, which is

1 what's known as LDL, low-density lipoproteins. You've all  
2 heard hopefully of good cholesterol and bad cholesterol. So  
3 HIV itself can impact that.

4 Many of the HIV medications -- not all, but many of  
5 them can impact the lipid in an adverse way. So you have a  
6 double whammy there. Number 1, HIV may impact it. Doesn't  
7 always but it may.

8 Number 2, many -- not all -- of the medications may  
9 have a negative impact on the lipid profile of a person.

10 Then there's a third whammy as well, that many of our  
11 treatments for elevated lipids, cholesterol, triglycerides,  
12 may not work as well in patients with HIV infection.

13 So it's really a triple whammy. They're at risk for  
14 the disease from HIV itself. They're at risk from the  
15 medications, some of them that we used to treat HIV, and then  
16 even if they get it, they're at risk for not responding as  
17 well to some of these lipid-lowering agents.

18 Q. When you say "lipid-lowering agent," what does lipid  
19 encompass so the jury understands? Is that kind of an  
20 umbrella term for some other --

21 A. Yeah. For practical purposes, we can use this for  
22 triglycerides and cholesterol, from a practical point of view.

23 Q. All right.

24 So when you said "lipid," you're referring to both  
25 triglycerides and cholesterol.

1 Fair?

2 A. Correct.

3 Q. Okay.

4 And you mentioned all of these kind of compounding  
5 factors that kind of put HIV patients behind everybody else  
6 when it comes to these issues.

7 What are the risks of high cholesterol, high lipids,  
8 especially in these types of HIV patients?

9 A. So this is very well understood, both in HIV as well as  
10 in nonHIV patients, that having a bad lipid profile, that puts  
11 you at risk for significant what we call cardiovascular  
12 complications.

13 Basically, the blood vessels get clogged in different  
14 parts of the body, and that can lead, most importantly, to  
15 heart disease, but it can lead to stroke. It can lead to  
16 kidney dysfunction. It can lead to peripheral vascular  
17 disease, troubles with your blood vessels to your legs.

18 It can really impact your entire body. That's why so  
19 many people across the country are on various lipid-lowering  
20 agents and why that's made such attention -- people diet,  
21 exercise -- lipid-lowering agents and trying to prevent these  
22 complications from occurring.

23 We've learned a tremendous amount about this in the  
24 last number of decades.

25 Q. Dr. Glatt, we're going to talk more about this as we get

1 into your opinions, but just for now, in terms of other health  
2 risks for these HIV patients, where would you generally rank  
3 heart disease and high lipids in the hierarchy of what you're  
4 considering as a physician?

5 A. So that -- it goes right up towards the top. There are  
6 published papers that state that. That's not just me talking.  
7 There are published papers that state that taking a look at  
8 the lipid profile is as important as the efficacy.

9 So it's very important.

10 Q. I want to shift gears and talk about some of the sources  
11 that physicians that are treating HIV patients look to to make  
12 prescribing decisions.

13 So let's start with the FDA label. What is the FDA,  
14 the Food and Drug Administration?

15 A. So the Food and Drug Administration is a federal agency  
16 that is supposed to protect us. Its charter is to make sure  
17 that the medications that are approved, that require approval  
18 are appropriately studied for both safety and efficacy. Do  
19 they work? Are they safe, and do they work?

20 And their organization is chartered by the  
21 United States Government to make sure that appropriate studies  
22 are done, and we don't do what we just -- sounds like it's a  
23 good idea, but we do rigorous studies, Phase 1, Phase 2,  
24 Phase 3 trials, each expanding in size and in the rigorousness  
25 of the studies.

1 And then they're submitted to the FDA for their  
2 judgment, evaluation of those studies. They'll come back  
3 sometimes and say, No, you need to do this, you need to do  
4 that or they'll critique them in a more minor way.

5 And then they will get approved by the FDA, and that is  
6 then called an FDA-approved indication, which then makes the  
7 label for that drug, and that's how a drug gets approved, and  
8 that is how it's supposed to be used, according to the label.

9 Q. Dr. Glatt, you mentioned kind of the level of information  
10 that a pharmaceutical company has to submit to the FDA to get  
11 an approved label for a certain -- you say indication. You  
12 mean use.

13 Right?

14 A. Yes. Indication, use, same thing.

15 Q. Would you -- would those typically be what you would  
16 consider in the science world like the gold standard study,  
17 double placebo, controlled, blind stage 3-type studies?

18 A. Right. The studies for almost all of the HIV medications  
19 to get approval are what we call a double-blind prospective  
20 randomized trial. That's a big bite.

21 What it means is that -- "double blind" means both the  
22 patient and the doctor don't know what drug their patient is  
23 receiving. Even if I'm an honest person, if I know that  
24 patient A is getting the drug and patient B is not getting the  
25 drug, I will be biased to think -- if I think the drug works,

1 that patient A is doing better than he really is and patient B  
2 is not doing as well.

3 And if the patient knows what they have, they may or  
4 may not attribute their side effect to an inactive drug versus  
5 a sugar pill. So that is the gold standard, double blind.

6 The patient and a doctor don't know what they're  
7 getting, and it's prospective. That means we're starting off  
8 from .0, and let's see what happens. It's randomized.

9 It means I don't know which patient is going to get  
10 which one. So I have no idea what my patient is going to be  
11 getting. The patient has no idea what they're going to be  
12 getting.

13 And then you look at it for a significant period of  
14 time in what we call a statistically powered machine, meaning  
15 you need to have a statistician state, This is the number of  
16 patients we would expect to need in the study for this study  
17 to be powered, to have the ability to make the conclusion that  
18 we're trying to make.

19 And that's the gold standard, and for all of the drugs,  
20 including the ones that we're discussing today, those studies  
21 were done. They're expensive. They take a lot of time, and  
22 that's the gold standard, and that's how you get FDA approval  
23 for something.

24 Q. And just so we're clear, you said those studies were  
25 done. But studies can be done for a particular use, like a

1 limited use of a drug.

2 Is that fair?

3 A. Exactly. Yeah.

4 Q. And we'll talk more about that.

5 So once this study is done, you said that the purpose  
6 is you've now deemed -- you get a label and it's deemed safe  
7 and effective.

8 Is it for what the label says you can use it for?

9 A. The FDA approval is specifically for what the label says.

10 Q. Is there different parts of the label that are more or  
11 less important or more or less need to be followed, or is all  
12 of the label there to guide physicians in terms of what is  
13 safe and effective?

14 A. Everything in the label is important.

15 Q. How does the label relate to how pharmaceutical companies  
16 are allowed to market their products to physicians?

17 A. So pharmaceutical companies are only allowed to market  
18 their product in their formal marketing fashion that they're  
19 allowed to do following the label. They are not allowed to  
20 market drugs in a called off-label fashion.

21 Q. And do you have a -- do you have an understanding for why  
22 the FDA requires that before?

23 A. Sure.

24 Q. Explain that to the jury.

25 A. So, again, FDA is our protector. FDA is supposed to make

1 sure that we use drugs right, and as a physician, that is a  
2 major guide, but as a pharmaceutical industry, that is the  
3 sole guide. That is all that they are approved to go and  
4 market that product. Physician has a little bit more leeway,  
5 but the FDA --

6 MS. BROWN: Your Honor?

7 THE COURT: Yes, Ms. Brown.

8 MS. BROWN: I apologize. Your Honor, I object to  
9 this line of questioning. Outside the scope.

10 THE COURT: Let me see you at sidebar.

11 (Sidebar begins at 2:40 p.m.)

12 THE COURT: Let me hear the full objection.

13 MS. BROWN: Thank you, Your Honor. So the question  
14 was, Why does the FDA require that promotion has to be  
15 on-label, Your Honor.

16 That's a regulatory opinion that he's not qualified to  
17 give, that he wasn't disclosed on, and those opinions don't  
18 appear in his report.

19 MR. WIRMANI: They do appear briefly, and that's how  
20 I'm questioning him. He does say in his report the purpose of  
21 the FDA is to make sure the drugs are safe and effective and  
22 that by requiring pharmaceutical companies to bring the gold  
23 standard studies, it makes sure that they actually do all of  
24 the research before they go out and sell a drug, and he says,  
25 Otherwise, the pharmaceutical companies, they can just get a



1 small indication and go market the drug. They would have no  
2 motivation to complete the other studies, and he says that  
3 that's the reason for that.

4 It's brief, but it was definitely in his report, and  
5 but it wasn't challenged, Judge.

6 THE COURT: Where does it say in the report the  
7 purpose of why the FDA requires off- -- prohibit off-label  
8 marketing -- is that the question?

9 MS. BROWN: Correct, Your Honor.

10 THE COURT: Where in the report does it say that,  
11 because I don't have the report before me?

12 MR. WIRMANI: Can I grab a copy, Judge?

13 THE COURT: You may.

14 (Brief pause.)

15 (Sidebar was concluded at 2:42 p.m.).

16 (Open court.)

17 THE COURT: This is going to take a few minutes,  
18 folks. We are going to take our ten-minute break so that the  
19 jurors can stretch and not waste time waiting for me to make a  
20 ruling on an issue.

21 So why don't we have the jurors dismissed, and then  
22 we'll be in recess for ten minutes or so.

23 THE DEPUTY COURT CLERK: All rise.

24 (Jury exits the courtroom.)

25 (Sidebar begins at 2:43 p.m.)

1 MR. WIRMANI: Judge, it is paragraphs 44 through 49.  
2 There is a discussion about the FDA process and its purpose  
3 and how this encourages drug companies, and it wasn't  
4 challenged, Judge, and in federal court, you've got to file a  
5 Daubert motion to challenge an opinion.

6 THE COURT: Well, you can't challenge something if  
7 you don't believe it's in the report in the first place.

8 MR. WIRMANI: Yeah, of course. Of course.

9 THE COURT: So that doesn't make any sense to me,  
10 that argument. So let me just take a look and see if it's in  
11 here.

12 MR. WIRMANI: Yes.

13 THE COURT: You're right, if I agree with you that  
14 this touches on what he testified, well, then you're right.  
15 Then we move on. 43 through what?

16 MR. WIRMANI: 44 through 49, Judge.

17 THE COURT: Okay.

18 (Brief pause.)

19 THE COURT: Before I get to the next paragraph,  
20 Ms. Brown, 44 is -- it starts off saying, "Drug manufacturer  
21 prohibits from promoting or marketing drugs for off-label use  
22 or indication. This stems from the concern that off-label" --

23 MS. BROWN: Sure.

24 THE COURT: So he is talking about why drug  
25 manufacturers are prohibited from marketing drugs off-label.

1 MS. BROWN: And I don't object to him saying they  
2 cannot promote off-label. I did not object to that question.

3 The second question was: Do you have an understanding  
4 of why the FDA does that? He has no experience working with  
5 the FDA.

6 THE COURT: But it's here. Just look.

7 MS. BROWN: I know --

8 THE COURT: Just -- wait. Let me finish. "This  
9 stems from the concern that off-label utilization has not  
10 passed screening by the FDA and has frequently not been shown  
11 to be safe and effective, legitimate controlled clinical  
12 trial." So he's giving a reason also as to why it's  
13 prohibited.

14 MS. BROWN: I don't think that's an opinion of what  
15 the FDA -- the reasons for the FDA regulations, which is what  
16 he was asked. He was asked specifically why the FDA regulates  
17 that.

18 THE COURT: How do you interpret this concern? When  
19 you read this -- before I get to the next one --

20 MS. BROWN: Yep, yep.

21 THE COURT: -- where is that concern coming from?

22 MS. BROWN: I honestly have no idea. His concern is  
23 not cited. We have no idea.

24 THE COURT: I'll take a look. What's the next  
25 paragraph?

1 MR. WIRMANI: 44 through 49.

2 THE COURT: All right. I hear the objection, but  
3 based on my review of those paragraphs, 44 through 49, I think  
4 it's covered. He can answer that particular question. I  
5 don't know how much farther we're going into that.

6 MR. WIRMANI: One more.

7 THE COURT: I'm going to overrule that objection.

8 MR. WIRMANI: Just so we can resolve it now, the only  
9 other question I'm going to ask is about the reasons that they  
10 have that pharmaceutical companies go and get a full label  
11 approval without going to market. That's why they require for  
12 each step of the way --

13 THE COURT: Sorry. Say that slower and again.

14 MR. WIRMANI: So his next -- very next line at  
15 paragraph 44, Your Honor, he talks about "If a company could  
16 market a drug for any use once it has been approved by the FDA  
17 for any indication, there would be a motivation for companies  
18 to conduct very limited studies."

19 THE COURT: You want to elicit that?

20 MR. WIRMANI: That's the only other thing I'm going  
21 to elicit on this topic.

22 THE COURT: Okay. I mean, I'm going to prohibit him  
23 from eliciting --

24 MS. BROWN: It's -- it's -- I have no objection if  
25 that's his opinion, but if it's couched as why the FDA is

1 putting these, I just don't think he's qualified for that,  
2 Your Honor. He's never worked with the FDA.

3 THE COURT: Yeah. This motivation is his opinion,  
4 not the FDA's opinion.

5 MR. WIRMANI: His opinion about why the FDA does it.  
6 I mean, you don't have to work at a Government agency to have  
7 an opinion about the regulations.

8 THE COURT: Let me look at it first. Both of you  
9 guys, don't -- I know you're about to argue with each other,  
10 but let me look at it for a moment.

11 Again, as I read beyond paragraph 44, Ms. Brown, I  
12 think it's covered. So you can take a look at it. I do note  
13 your objection, but I'm going to overrule.

14 I'm going to allow that second question based in  
15 totality of those paragraphs, and I believe what he's saying  
16 there is this is a concern for the FDA.

17 MS. BROWN: Okay. I understand.

18 THE COURT: It's beyond paragraphs 44, but as I read  
19 them in totality, to me, it's clear that there was sufficient  
20 notice to Janssen --

21 MS. BROWN: I understand.

22 THE COURT: -- that the argument is that he's saying,  
23 Look, this is a concern for the FDA, not just his personal  
24 concern of him as an expert.

25 So -- but those are the two areas, Mr. Wirmani?

1 MR. WIRMANI: That's all.

2 THE COURT: All right. So the objection is noted.

3 It's overruled. Why don't you guys take a few minutes to take  
4 a recess, though, and then I'll get the jurors back.

5 (Sidebar was concluded at 2:48 p.m.)

6 (Open court.)

7 (A short recess occurred.)

8 THE COURT: Remain seated.

9 THE DEPUTY COURT CLERK: All rise.

10 (Jury enters the courtroom.)

11 THE COURT: All right, folks. Be seated.

12 You can continue, Dr. Glatt. Just a reminder you are  
13 still under oath.

14 MR. WIRMANI: Thank you, Your Honor.

15 BY MR. WIRMANI:

16 Q. Dr. Glatt, before the break, I believe I was asking about  
17 the FDA and its role in relation to pharmaceutical companies.

18 Is that correct?

19 A. Yes.

20 Q. And my question to you is, do you have an understanding  
21 of why the FDA has these rules that are black and white and  
22 don't let pharmaceutical companies market beyond the label for  
23 the studies that they've submitted and got approval for?

24 A. Sure. So the FDA is supposed to protect all Americans  
25 from potentially dangerous medications unproven for those

1 therapies that medicines might be prescribed for, and that's  
2 why they're charged with making sure that studies are done,  
3 appropriate studies, scientifically rigorous studies with  
4 appropriate statistical and other evaluations, to make sure  
5 that those studies support the usage of those medications in  
6 practice.

7 And the pharmaceutical industry is required, based upon  
8 the FDA rulings and regulations, to market their drugs only  
9 based upon the label.

10 Q. Dr. Glatt, do you have an understanding as to why a  
11 pharmaceutical company is not allowed to get an indication for  
12 a limited use of a drug and then just go market it for all  
13 purposes?

14 A. Sure.

15 Q. And what is your understanding of that, sir?

16 A. So the pharmaceutical industry is a business. We work  
17 very closely with them. They're essential towards developing  
18 new drugs, but they're a business, and their goal is to sell  
19 as much of their product as they possibly can.

20 Obviously, from their perspective, they would like the  
21 drug to be used for everything that they feel legitimately or  
22 otherwise should be prescribed their drug. The FDA's purpose  
23 is to restrict that to only allowing it to be marketed for  
24 things that have been proven.

25 Q. And if something -- well, let me ask this way.

1           Would it discourage further research by pharmaceutical  
2 companies if a small indication equated to the ability to  
3 market for all purposes?

4   A.   Absolutely. There would be no incentive for them to do  
5 the appropriate studies, to scientifically prove what they're  
6 trying to have their drug marketed for. And that's why there  
7 are changes in the label and the companies go and do  
8 additional studies that then demonstrate that their product  
9 can be used for an additional indication.

10   Q.   And you're a practicing doctor, so you, obviously,  
11 understand that the FDA does not regulate your practice of  
12 medicine. And is it your understanding that under your  
13 medical license, in your judgment, that you could prescribe  
14 drugs off-label for certain patients?

15   A.   Yes.

16   Q.   Okay.

17           And why can doctors prescribe off-label but  
18 pharmaceutical companies can't market off-label?

19   A.   So my understanding of that would be that I have no  
20 financial benefit from whether I prescribe drug A or drug B.  
21 I do so based upon what I think is best for my patient. And  
22 if in my professional opinion I think that this drug may have  
23 an indication that hasn't yet been approved by the FDA, so I  
24 have the right, as a physician, to make that decision based  
25 upon all of the scientific evidence, my personal experience,



1 and other factors.

2 I have no financial incentive to go and prescribe that  
3 drug off-label. The pharmaceutical industry has a tremendous  
4 financial incentive to have their drug purchased, used by more  
5 people.

6 Q. And, Dr. Glatt, have you personally prescribed drugs  
7 off-label during the course of your almost 40-year career?

8 A. Absolutely.

9 Q. What does a physician need when they're looking at the  
10 label and all the other guidelines? What does a physician  
11 need in terms of medical judgment to then decide I need to go  
12 off-label?

13 A. So first of all, a physician needs to know what they're  
14 doing. They really need to understand why there isn't an  
15 indication that is on the label, what is different about this  
16 particular patient, or this particular condition in this  
17 particular patient, that would necessitate not using, if there  
18 is, an FDA-approved drug, and why they choose, in this  
19 particular situation, to use a different drug that doesn't  
20 have such an FDA indication.

21 Q. And we see here on the screen some guidance from the FDA.  
22 It says that physicians -- "If physicians use a product for an  
23 indication not in the approved labeling, they have the  
24 responsibility to be well informed about the product, to base  
25 its use on firm scientific rationale, and on sound medical

1 judgment," and then they've got to maintain records.

2 Do you agree with that guidance in terms of when it is  
3 and is not appropriate for a physician to prescribe a drug  
4 off-label?

5 A. Absolutely.

6 Q. Is -- is the -- is that dichotomy, the ability for  
7 physicians to prescribe off-label but pharmaceutical companies  
8 can't market, does that, in your view, create any heightened  
9 duty on pharmaceutical companies to make sure that what they  
10 are providing to doctors is truthful and accurate?

11 A. Absolutely.

12 Q. Explain that for the jurors, please.

13 A. So I think it's very important to know that it's illegal  
14 to market off-label. That's number one. I think it's  
15 unethical to market off-label.

16 And then if a physician wishes to get additional  
17 information, there are many legitimate, appropriate ways for a  
18 physician to get additional information about a particular  
19 medication. It shouldn't be provided by a marketing  
20 representative who is not qualified, trained, or appropriate  
21 to tell a physician to use an off-label indication.

22 And there are ways for physicians independently, and  
23 even through the pharmaceutical industry, to get that  
24 information if they feel it's necessary.

25 Q. And in order to be well informed, have a firm, scientific

1 rationale and have sound medical evidence, is it important  
2 that doctors receive accurate, developed information if it's  
3 given to them by the pharmaceutical industry?

4 A. Absolutely.

5 Q. You work at a hospital. Do you personally allow  
6 pharmaceutical reps to come into the hospital and talk to your  
7 doctors?

8 A. I do not.

9 Q. Why don't you?

10 A. I don't think it provides any medical benefit. I think  
11 that these are basically salespeople. They're not there to  
12 train physicians; they're not there to educate physicians.  
13 With the advent of the internet and with the advent of easy  
14 searchability, it is of very limited usage for me to have a  
15 conversation with any pharmaceutical representative.

16 That doesn't mean that I wouldn't engage with a  
17 pharmaceutical company in a research project. It doesn't mean  
18 that I wouldn't engage with physicians or PhDs to find out --  
19 or to perform possibly a study related to their medication.

20 Q. And you work in an academic setting. Is that fair? It's  
21 a teaching hospital?

22 A. Yes.

23 Q. Is there a distinction, based on your experience, between  
24 how teaching institutions view information from pharmaceutical  
25 companies and kind of what goes on in private practice?

1 A. Sure. We're highly regulated. And even if we weren't,  
2 we would highly regulate ourselves.

3 I, again, strongly recommend that pharmaceutical  
4 representatives do not come in to speak with my doctors, and  
5 they don't in the hospital itself, to my knowledge. What  
6 happens in private doctors' practices is not under my purview  
7 or control.

8 I think that if I wished to get information about  
9 something, there are very good people in the hospital that can  
10 help me obtain information through searches of the internet.  
11 We have staff that can help provide us with that. We have  
12 other experts that I can go to. There are professional  
13 resources available in the professional societies. Those  
14 severely trump the ability of a pharmaceutical representative  
15 to give me information. They're not trained or qualified to  
16 do that.

17 Q. Has -- you've been in a teaching context, right, a  
18 teaching institution for most of your career.

19 Is that fair?

20 A. Correct.

21 Q. Has -- has skepticism in the academic community as  
22 opposed to the private practice community, has it increased  
23 over time related to these practices and pharmaceutical  
24 companies giving information?

25 A. Absolutely. Every single person who gives a lecture

1 that's under our domain and for which you get continuing  
2 medical education credit, what we call CME, so every one of  
3 those speakers must sign and must disclose any conflict of  
4 interest, whether it's pertinent to their talk or not. So  
5 they must state whether they're being paid by a pharmaceutical  
6 industry to provide their opinion. Even if it's unrelated to  
7 the opinion that they're providing, if they have a conflict of  
8 interest, they must state it.

9 We will not give CME, continuing medical education,  
10 credits to anybody that doesn't sign such a conflict of  
11 interest form. We require that that be part of their lecture,  
12 to state this is or is -- I have no conflict of interest or  
13 these are my conflicts of interest.

14 We only allow in the hospital what we call CME  
15 lectures. Our grand rounds are only CME lectures. We do not  
16 allow any of the, quote, speaker program talks to occur in the  
17 hospital. At least to my knowledge, that doesn't occur.  
18 Certainly not in my department that wouldn't occur.

19 Q. Why is that important to you as the head of the hospital?  
20 Why do you -- why do you want them to fully disclose? Even if  
21 it's not related to what they're talking about, why do you  
22 want that disclosure for the audience?

23 A. Because there's always bias. There's always unrecognized  
24 bias. We understand that if somebody is being induced in some  
25 way, shape, or form, that may impact -- even if they're

1 honest, good people, which they aren't necessarily always  
2 honest, good people -- even honest, good people will  
3 potentially be biased without even recognizing it.

4 And that's why it's important that the audience  
5 understand and know any conflicts of interest that are  
6 present. And then the audience can make decisions about what  
7 information is provided and take that conflict of interest  
8 into consideration.

9 I personally will not allow a speaker who has a  
10 conflict of interest to talk on the subject that they have a  
11 conflict of interest in.

12 Q. And taking us to the relevant time period, 2006 to 2014,  
13 based on the standard of care and the available medications on  
14 the market, how common was it for a doctor to need to go  
15 off-label to treat any particular HIV patient?

16 A. The guidelines are excellent guidelines from that period  
17 of time. They're, again, large bodies of expert physicians,  
18 highly experienced in HIV, that came up with these guidelines,  
19 two separate groups of experienced, senior and knowledgeable  
20 physicians.

21 The guidelines take into account the vast majority of  
22 patients and situations, and, therefore, one should in  
23 general, not absolute, but one should in general use those  
24 guidelines. You're not obligated to follow them. There are  
25 exceptions to the rules. But in general, most patients will

1 fit into the guidelines, into the scheme of how those drugs  
2 should be prescribed. There are always going to be  
3 exceptions.

4 Q. And is that maybe different than it was in the 1980s,  
5 when these diseases were first being addressed and drugs were  
6 coming on the market very quickly and people didn't understand  
7 them as well?

8 A. Well, the guidelines, you know, take into account the  
9 best state of the art. But until 1987, we had no therapies,  
10 so there were no guidelines on how to treat patients for  
11 underlying HIV because there were no drugs available.

12 Q. And we're going to talk to about the guidelines in a second,  
13 but last question about the label.

14 In terms of a prescribing decision, how important is  
15 the label to you as a physician in prescribing a medication?

16 A. So it's very important. But the guidelines help guide me  
17 to understand. A label can be thought of as that particular  
18 drug, but it doesn't compare it in great detail to other  
19 potential treatment applications.

20 So a drug may have an indication for something, but it  
21 may be the fourth, the fifth, or second-best choice. And  
22 guidelines take all of the drugs and their labels and their  
23 usages in the studies that have been done and come up with  
24 consensus, recommendations. Not absolute, but excellent.

25 Q. And when we're talking about the guidelines, let's start

1 with the DHHS guidelines.

2 What does DHHS stand for?

3 A. So it stands for the Department of Health and Human  
4 Services. And that's an expert panel of physicians highly  
5 experienced in the treatment of HIV infection. And they came  
6 up with guidelines and updated them constantly during the  
7 relevant period of time and before and afterwards.

8 Q. Just so we're clear, the guidelines are not part of the  
9 label.

10 Is that fair?

11 A. Correct.

12 Q. Okay.

13 In your experience, you've worked with these guidelines  
14 for a number of years. Are the guidelines -- like, what's the  
15 interaction between the label and the guidelines? Are the  
16 guidelines almost always consistent with the label?

17 A. Almost always, yes.

18 Q. Okay.

19 And so what do the guidelines add?

20 A. So the guidelines give you the additional expertise,  
21 recommendations, guidance between the different labels. You  
22 may have five drugs that are approved for this indication from  
23 the FDA, but there's a pecking order. There's a hierarchy  
24 that the guidelines may suggest, this is the preferred agent  
25 or agents to use. And sometimes they'll have no preference



1 one versus the other and they will say, Well, let's list them  
2 in alphabetical order, but these are the two preferred agents.

3 Then there may be specific situations in which those  
4 agents are not preferred, and they'll give alternate agents  
5 that may be for specific patient characteristics or because of  
6 failures of therapies or because of drug resistance or for  
7 many other reasons.

8 Q. So would it be fair to say that the guidelines are  
9 looking at the on-label use of various different drugs and  
10 then, within that box, giving guidance to physicians how to  
11 rate them or how to use them in a particular situations?

12 A. Exactly.

13 Q. What are the IAS recommendations, the International AIDS  
14 Society, recommendations?

15 A. So that's another major consensus group of very highly  
16 trained and experienced HIV treating physicians who came up  
17 with a different set of guidelines, although they're very,  
18 very similar, and they publish them in the journal, the  
19 American Medical Association, one of the premier journals, and  
20 they also get updated on a very regular basis. And that's  
21 another set of guidelines.

22 Again, guidelines mean just that: They're guidelines,  
23 but they're solid and they're good and they fit most patients.

24 Q. And do they operate similar to the DHHS guidelines in  
25 terms of looking at different on-label uses and then helping a

1 physician decide where within the on-label uses it should fall  
2 with a particular patient?

3 A. Again, exactly. Yes.

4 Q. And the IAS guidelines, or IAS society recommendations,  
5 those are off-label just like the DHHS guidelines.

6 Correct?

7 A. When you say "off-label," I don't understand what you  
8 mean.

9 Q. They're not part of the label of any particular drug.

10 A. No. They're recommendations from the society. They take  
11 into account the label, but they theoretically could recommend  
12 something that would be off-label as well.

13 Q. And in your experience, is that common, where they  
14 recommend something off-label?

15 A. Very unusual.

16 Q. Are you familiar with what is known as the "compendium"?

17 A. Yes, I am.

18 Q. Okay.

19 What are these sources: DrugDex and the AHFS Drug  
20 Information Manual?

21 A. So these are resources that, not necessarily only, but  
22 are predominantly used by pharmacists, I believe. And they  
23 really are providing another repository of information about  
24 these drugs, focusing, again, on things that a pharmacist  
25 would need to know, but are perfectly useful for clinicians as

1 well.

2 Q. And in your experience, do these compendium manuals, do  
3 they follow the label as well?

4 A. Absolutely.

5 Q. I want to shift gears. I want to get into kind of some  
6 of your opinions.

7 So let's start with the drug Intelence. Okay. Tell  
8 the jury: What type of drug is Intelence?

9 A. So Intelence is falling into the category of the NNRTIs,  
10 the non-nukes, if I can use the vernacular. And that's a  
11 class of drugs that has a different mechanism than actually  
12 the nukes and protease inhibitors, which were the three main  
13 classes of drugs, although there were six or seven, depending  
14 on how you divide it up, classes of drugs during the relevant  
15 period of time.

16 And they are a -- you know, always used with usually  
17 two, sometimes more, other drugs to go and make these  
18 cocktails, these combinations of drugs that would be able to  
19 hopefully adequately treat without too many side effects and  
20 prolong patients' lives with HIV, reverse their  
21 immunosuppression and allow them to live normal lives as best  
22 as possible.

23 Q. And when was Intelence -- when did it first come to  
24 market, if you recall?

25 A. Yes. It first came to market in 2008.

1 Q. October 2008? Does that sound about right?

2 A. Yes.

3 Q. What was Intelence -- or what is Intelence indicated for  
4 by the FDA?

5 A. So Intelence is specifically and only indicated by the  
6 FDA for the treatment of experienced patients -- that means  
7 patients that have already been treated with antiretroviral  
8 therapy -- plus they have to have significant resistance  
9 mutations. They have to have specific resistant patterns in  
10 at least two categories of the classes of drugs. That's a  
11 very niche, good but niche drug, and it should be utilized  
12 specifically in those situations according to the label, but  
13 as well according to the guidelines.

14 Q. And when you say "niche drug" and it says  
15 "treatment-experienced," is it -- it sounds like what you're  
16 saying -- I just want to be clear -- is it all  
17 treatment-experienced patients, or is it a certain type of  
18 treatment-experienced patient?

19 A. It's a small subset of treatment-experienced patients,  
20 specifically those that have a mutation in that class as well  
21 as a mutation in another class of drugs.

22 Q. And what does the label for Intelence say about how it's  
23 supposed to be dosed?

24 A. The label states, as well as all the guidelines, as well  
25 as the compendia, as well as every other documented resource,

1 that it must be given twice daily.

2 Q. And to your knowledge, have those two things,  
3 treatment-experienced and twice-daily dosing, have they ever  
4 changed?

5 A. No, they have not.

6 Q. Even today?

7 A. Even today.

8 Q. How does the label relate to the underlying studies? In  
9 other words, if the label says dose twice a day or  
10 treatment-experienced, is that the population and the way it  
11 was used in the underlying study?

12 A. Yes.

13 Q. Okay.

14 Can you just explain that to the jury how that works,  
15 how the -- you have to look at the study and then that becomes  
16 what is ultimately deemed safe and effective?

17 A. Sure.

18 So when a drug is being developed, you do phase 1  
19 studies, which are smaller studies, and it's often in healthy  
20 people, to see how the drug works and how toxic it is and what  
21 are the -- what we call the pharmacokinetics, to see how the  
22 drug would be dosed, how frequently, and what are  
23 complications of it.

24 Once it's established that it's safe and we know how to  
25 dose the drug as best as possible, you start doing it -- using

1 it in small studies in people with that disease that you're  
2 marketing it for.

3 And then when you're ready and you think you have a  
4 drug that might work, you do the larger, prospective, what are  
5 called Phase 3 double-blind, prospective -- it doesn't  
6 absolutely have to be, but that's the standard that you'd like  
7 to have, a double-blind, prospective study and hundreds of  
8 patients in the treatment arm and hundreds of patients in the  
9 control arm.

10 The control arm may be patients taking a sugar pill if  
11 you don't have accepted treatment, so it's a placebo, or if  
12 there is an accepted treatment, the control arm would be the  
13 standard accepted therapy or one of the several standard  
14 accepted therapies, was this your treatment -- your  
15 prospective good treatment.

16 And then you do the study. And it's a double-blind, so  
17 nobody knows whether they're getting it; the doctors and the  
18 patients don't know. You do it for a significant amount of  
19 time in a significant number of patients, and then you analyze  
20 it. And if, lo and behold, it works, so then you can submit  
21 that data to the FDA and get an indication for your drug.

22 Q. So when we say, like, Intelence's label says dose twice  
23 daily, that means because that's how it was studied in the  
24 patients.

25 Is that fair?

1 A. Correct.

2 Q. Okay.

3 And you've already talked about this being a niche  
4 market. Is it fair to assume that Intelence being a niche  
5 market in terms of the treatment-experienced of the patients,  
6 that that limited its marketability in the patients that  
7 doctors could use it on?

8 A. Absolutely.

9 Q. What about once-daily -- or twice-daily dosing? How did  
10 that impact the marketplace for this drug and how popular and  
11 attractive it was to doctors and patients?

12 A. So that's an important factor in terms of adherence as we  
13 discussed earlier. It's easier to take a pill once a day than  
14 it is twice a day, especially when some of the pills you're  
15 taking are once a day and some of the pills you're taking are  
16 twice a day. It just gets confusing. We all have taken pills  
17 and, you know, you can sometimes take the wrong pill twice and  
18 the right pill once. It can be confusing. Not impossible,  
19 but it can be more confusing.

20 So everybody tries, as I've mentioned, to give all of  
21 the drugs once a day if possible.

22 The main competitor of Intelence, the drug that was  
23 recommended as a preferred treatment from that class, from the  
24 non-nuke, the NNRTI class, was a once-a-day drug that was  
25 actually available in a single pill with two other agents,

1 known as Sustiva as the NNRTI and Atripla as the combination  
2 of three drugs in one pill once a day.

3 And they didn't have that. And, therefore, it was a  
4 competitive advantage, if you just look at it from a pure  
5 marketing point of view, for their competitor.

6 Now, if there was a difference in the efficacy of the  
7 drugs, that would make up for it more complex, but they were  
8 equally efficacious, and that's why you reserved Intelence.

9 And the guidelines, again, specifically state, Do not  
10 give this drug in a naive patient. That's the guidelines of  
11 people that are not getting paid by the drug company. These  
12 are independent experts in the field consistently, in both  
13 guidelines, state, Do not give this drug in treatment-naive  
14 patients. Give it twice a day, not once a day, when you are  
15 giving it in the niched area.

16 Q. And, Doctor, we'll talk about the treatment-naive claim  
17 and the guidelines in a little bit. I want to start with the  
18 first of Janssen's marketing messages.

19 "Intelence is safe and effective to be dosed once a  
20 day."

21 Have you examined that marketing representation and  
22 then compared it to the label, the guidelines, and the  
23 compendium?

24 A. Yes, I have.

25 Q. Okay. Let's go through each of these so the jury



1 understands the basis for your opinion.

2           So starting with the label, is that the Intelence label  
3 that we see --

4 A.    Yes.

5 Q.    -- there?

6 A.    Yes.

7 Q.    And how does it indicate that Intelence should be dosed?

8 A.    It specifically states that you should be taking 200  
9 milligrams, which initially was two 100-milligram tablets  
10 twice a day, once in the morning and once in the night,  
11 ideally 12 hours apart, but patients find that sometimes very  
12 difficult, but twice daily. And actually you should take it  
13 following a meal, which makes it a little bit more complicated  
14 because it's better absorbed when you take it with a meal.

15 Q.    Now, is there anything in that label that supports or has  
16 a study that would justify once-daily dosing?

17 A.    The label specifically states to take it twice a day.

18 Q.    Is there -- we've heard that there's information within  
19 the label about the half-life of the drug. Why is the  
20 half-life not sufficient to jump to the conclusion that  
21 once-daily dosing is appropriate?

22 A.    Because you have proven that it works. You know, in  
23 medicine there are a lot of good ideas and a lot of nice, wow,  
24 that sounds like the right thing, and then you do a study and  
25 they show that it's actually dangerous or that it doesn't

1 work.

2 So the half-life of a drug would be involved in your  
3 phase 1 studies to say, It makes sense to give this drug based  
4 upon the half-life in this way. Let's check it out.

5 That never was done in an adequate way to suggest that  
6 it could be given once daily.

7 Q. And if Janssen's sales representatives, as you know from  
8 reviewing the evidence, were promoting Intelence for  
9 once-daily dosing by referring to the half-life on the label,  
10 would you, in your expert opinion, consider that to be an  
11 illegal off-label message?

12 A. Correct.

13 Q. And why? Why can't you -- I mean, it sounds like they  
14 are looking at the label, so why can't they make that  
15 representation?

16 A. Because the half-life doesn't necessarily -- it doesn't  
17 mean it doesn't, but it doesn't necessarily correlate with  
18 dosing intervals.

19 Q. And to your knowledge, have those studies ever been done?

20 A. Not adequately.

21 Q. Not adequately?

22 A. No.

23 Q. All right.

24 Let's look at the DHHS guidelines and the IAS  
25 guidelines. What did they say during the relevant time period

1 about the dosing of Intelence?

2 A. They both say the exact same thing, that they are always  
3 recommended to be taken twice daily.

4 Q. And you mentioned they were -- Intelence was never a  
5 preferred or an alternative preferred drug under the  
6 guidelines. We'll talk about that in the treatment-naive  
7 context.

8 Now, is there some times where you see in the  
9 guidelines, like, a study that maybe is referenced that looked  
10 at a drug in a different way than the label, you know,  
11 once-daily dosing of Intelence, for example?

12 A. Guidelines might or might not, depending on the writers  
13 of the guideline, include studies that may or may not be in  
14 the label. They may or may not be good. May not be adequate  
15 because they're educational guidelines.

16 And they need to point out good as well as bad research  
17 or bad research that -- research that hasn't yet made it to  
18 the point of being significant enough because sometimes,  
19 physicians might think that this is good enough to make a  
20 conclusion.

21 So guidelines sometimes tell us that there is  
22 inadequate information, even though there may be slight  
23 information, to go and make a recommendation.

24 Q. Okay.

25 So if I understand correctly, the fact that a -- one of

1 these guidelines references a study is not an endorsement.

2 You have to actually look at what it says to do?

3 A. The only way you can say it's an endorsement is if the  
4 guidelines endorse it.

5 Q. And sometimes the guidelines will actually include  
6 studies just so doctors know it's bad information or not  
7 sufficient information?

8 A. Exactly.

9 Q. What about the recognized compendia? During the relevant  
10 time period, what did they say about the appropriate dosing of  
11 Intelence?

12 A. They say the exact same thing, that it must be dosed  
13 twice a day.

14 Q. And the same for both of those manuals?

15 A. Correct.

16 Q. Any support in either of those for once-daily dosing?

17 A. Absolutely not.

18 Q. Are you familiar with the DeJesus study and the  
19 evidence -- the allegations that show that salespeople were  
20 using this study, or at least the conclusions of this study,  
21 to lead doctors to believe that there is information that  
22 would support once-daily dosing of Intelence?

23 A. Unfortunately, I have.

24 Q. Have you reviewed the DeJesus study?

25 A. Yes, I have.

1 Q. Do you see issues with it?

2 A. I see numerous issues with it.

3 Q. Tell the jury what are the problems with the study and  
4 why it can't be relied on.

5 A. So the study is a very small number of patients that were  
6 enrolled for a very short period of time, and what the study  
7 actually showed is the concerns that I would have, and that is  
8 that you get higher levels when you give it once a day, and  
9 your minimal inhibitory concentration, which means towards the  
10 end of the study, the end of the day, is lower than when you  
11 give it twice a day.

12 And both of those two things are of concern, and the  
13 study is inadequately powered, doesn't have the statistical  
14 validity to say anything in a six-week period of time, when  
15 the drug actually wasn't given for that long, and for 23  
16 patients.

17 Again, I want to stress the patients who got the drug  
18 once daily had higher levels of the drug at the beginning, and  
19 they had lower levels of drug towards the end of that one-day  
20 treatment, which is exactly the concern I would have.

21 So not only does this not support it, in my opinion, it  
22 actually goes against it.

23 Q. And do you see a conflict of interest within the DeJesus  
24 study based on who the authors were?

25 A. Unfortunately, yes. It's certainly a potential for

1 conflict of interest when the majority of the authors are  
2 employed by the company.

3 Q. Okay.

4 And does the study indicate -- the disclosure statement  
5 indicate that Dr. DeJesus was a Janssen speaker and a Janssen  
6 consultant and he received grants from Janssen?

7 A. Yes, it does.

8 Q. Are there other authors of that study that also received  
9 grants from Janssen?

10 A. Yes, there are.

11 Q. And you mentioned -- and there's other speakers, too, in  
12 addition to Dr. DeJesus.

13 Correct?

14 A. Correct.

15 Q. You mentioned employees of the company. Does that say  
16 that some of these employees were also stockholders of  
17 Janssen?

18 A. It specifically states that three of them were full-time  
19 employees and stockholders. They have more than a vested  
20 interest in the marketability of the drug.

21 Q. Would you ever in your collective experience prescribe an  
22 HIV drug -- ever, ever rely on this study in making a decision  
23 to prescribe a patient Intelence once a day?

24 A. Absolutely not.

25 Q. Now, if you did not see the actual study, if you didn't

1 know how many patients were involved or the conflicts and you  
2 were only shared the conclusions -- and maybe not you, but  
3 another doctor was only shared the conclusions, could -- is it  
4 your belief that they could be misled because they don't know  
5 the vigor that went into the particular study?

6 MS. BROWN: Objection, Your Honor. Motion in limine.  
7 It's -- it's Daubert.

8 THE COURT: Let me read the question.

9 Sustained.

10 Mr. Wirmani, that goes right into the issue we  
11 sidebarred, so don't do it again.

12 BY MR. WIRMANI:

13 Q. Let's move on, Doctor.

14 In addition to the fact that once-daily dosing is  
15 off-label, do you have safety concerns about Intelence being  
16 dosed once a day during the relevant time period?

17 A. Yes.

18 Q. Let's walk the jury through what your concerns are.

19 A. So the study that we just showed demonstrated one of the  
20 concerns that I have, that the levels that you get when you're  
21 giving it at twice the recommended dose for twice daily,  
22 you're going to get too high levels, possibly.

23 And we don't know what those higher levels will do in  
24 terms of toxicity, both short term and long term. That's why  
25 you study a drug, to make sure that when you give it at that

1 higher dose once a day, that it will be safe as well as  
2 efficacious.

3 And that study that we just saw did neither of the two,  
4 and, in fact, the only way to demonstrate efficacy is to do a  
5 study on real patients. And the only way to demonstrate that  
6 there's a lack of toxicity is to do this for a longer period  
7 of time in an adequately powered number of patients in an  
8 ideally double-blind prospective study.

9 But that isn't the only type of study that would work,  
10 but certainly, you'd want to do a study that would show it's  
11 both efficacious as well as not dangerous.

12 Q. And you may have mentioned it, but you talked about the  
13 potential for toxicity if all of the dose is taken once.

14 Is there -- is there concerns on the flip side, that if  
15 you only take it once, it may not be in the system long  
16 enough --

17 A. Sure.

18 Q. -- to suppress the virus?

19 A. Sure. In fact, that study showed that minimum inhibitory  
20 concentration was lower when you gave it once a day towards  
21 the end of the dosing interval than when you gave it twice a  
22 day, which, again, goes along with the fact that the studies  
23 demonstrate it should be given twice a day.

24 The concern is if you're giving this as part of a  
25 cocktail and the patient is left uncovered for the last eight,



1 ten hours of the -- of the day, you're essentially give them  
2 an inadequate cocktail. You're giving them only the other  
3 drugs, and they could then develop resistance and then develop  
4 resistance further.

5 And that's why you want to do studies, to demonstrate  
6 that you're not hurting patients by giving them these  
7 regimens; that you're helping them.

8 Q. And, Doctor, during the reasonable time period, if the  
9 HIV physician wanted to prescribe an antiretroviral once a  
10 day, were there reasonable alternatives that were equally  
11 efficacious; in other words, equally effective at suppressing  
12 the virus?

13 A. Yes.

14 Q. What were those alternatives?

15 A. Even within that same class, Sustiva, efavirenz, was an  
16 NNRTI, a non-nuke, had a once-daily dosing regimen.

17 Within the other classes, the PI classes, they had  
18 once-daily dosing regimens, and they're all used with two  
19 nukes at the same time, all once-daily dosing.

20 So there were many options available if you wish to  
21 give a patient specifically a single daily dose of a  
22 medication.

23 Q. And those alternative options for once-daily dosing, had  
24 they already been proven safe and effective to the FDA?

25 A. Yes. All of them have that indication in their label.

1 Q. In terms of your ultimate conclusion about the claim --  
2 the marketing claim that Intelence can be dosed once a day, do  
3 you determine, in your expert opinion, that that is an  
4 off-label claim?

5 A. Absolutely.

6 Q. Okay.

7 And do you determine that it is not clinically  
8 appropriate?

9 A. Absolutely.

10 Q. And in terms of prescribing it once a day, do you find  
11 that that violates the accepted standard of care, the accepted  
12 standard of care in the HIV physician community during the  
13 relevant time period?

14 A. Yes.

15 Q. Your slides says that you come to that conclusion with a  
16 reasonable degree of medical certainty.

17 What does that mean?

18 A. Based upon everything that I know in medicine.

19 Q. Is that pretty certain?

20 A. As certain as one can be in medicine.

21 Q. Let's turn to Janssen's second marketing claim with  
22 respect to Intelence, that Intelence is safe and effective for  
23 treatment-naive patients.

24 Have you also examined that claim under the label of  
25 the drug and the various guidelines?

1 A. Yes.

2 Q. Let's look first at the Intelence label. Explain to the  
3 jury what is the indicated population for Intelence?

4 A. So there are two aspects of the indicated population.  
5 Number 1, they have to have been previously treated with  
6 antiretroviral therapy. So they're in the experienced group  
7 of patients, not in the naive group of patients.

8 But in addition to that, it's a very specific group of  
9 experienced patients, and as the label clearly states, they  
10 have to be resistant to an NNRTI, another drug within that  
11 class, and they have to have resistance to other  
12 antiretroviral agents, which usually will mean a PI.

13 What that basically means is that don't use this drug  
14 unless you meet those criteria. That's what the label says.

15 Q. And, Dr. Glatt, if you look at the bottom of that label  
16 there, does it actually say and inform physicians that the  
17 safety and the efficacy of Intelence has not been established  
18 in -- or excuse me -- in treatment-naive adults?

19 A. Correct. That's what it states.

20 Q. So given that, would the claim that Intelence can be  
21 dosed once a day -- would that be off-label, in your expert  
22 opinion?

23 A. Yes, sir.

24 Q. Let's look at the guidelines.

25 What did the DHHS guidelines say about using Intelence

1 in treatment-naive patients during the relevant time period?

2 A. So ETR, which you can see that's Intelence etravirine,  
3 that's a generic name, so it has not been studied in large  
4 randomized trials in naive patients, in patients who haven't  
5 been treated.

6 That's what the guidelines state. Those are the facts,  
7 and, therefore, it cannot be recommended. That's a strong  
8 statement to say it cannot be recommended as part of an  
9 initial therapy.

10 In fact, the guidelines go even further and state, Do  
11 not use it in this situation unless you meet the small niche  
12 population. And in my reading of the rebuttal comments from  
13 the expert, Dr. Rosenberg, he agrees with that 100 percent.

14 And he says, I've only used this in several patients  
15 myself in that very niche area.

16 Q. Just so since you brought it up, Dr. Glatt, when you say  
17 the rebuttal expert, Dr. Rosenberg, are you talking about  
18 another doctor that Janssen has hired as an expert witness in  
19 this case and that you expect or we expect will testify to  
20 this jury if they chose to bring him here?

21 A. I don't know if they'll bring him or not. I know that  
22 we -- he had testified previously and --

23 Q. I just want to orient the jury to what you're referring  
24 to when you say Dr. -- Dr. Rosenberg, so we understand.

25 A. Yes.

1 Q. And you mentioned this concept of the guidelines. Here  
2 there's an affirmative statement: Do not use Intelence in  
3 treatment-naive patients.

4 Did the guidelines also make recommendations you  
5 said -- and then prefer --

6 MR. WIRMANI: Bless you, Judge.

7 THE COURT: Thank you.

8 BY MR. WIRMANI:

9 Q. For preferred and alternative preferred drugs?

10 Tell the jury: What are those recommendations? What  
11 does that mean?

12 A. So the guidelines guide you. They tell physicians, We  
13 know this is very complicated, not all of you spend all of  
14 your days just taking care of HIV-positive patients. There  
15 are very few doctors that just do that.

16 And these experts who spent the vast majority of their  
17 career, their professional time caring for such patients have  
18 been invited. They're not part of industry. They're invited  
19 to give their professional opinion, and they have come to the  
20 conclusion and prefer using certain drugs in certain  
21 indications.

22 Now, there is a very similar drug to Intelence,  
23 Sustiva, that both of them are in the same class. There are  
24 other drugs in that class. Sustiva is better than the other  
25 drugs, and they have said that, of those other drugs and

1 including Intelence, the preferred agent to use is efavirenz.

2 Now, you can't use efavirenz because a woman might be  
3 pregnant, and that would be somewhat toxic in pregnancy, so  
4 then use a different NNRTI called nevirapine.

5 It does not recommend using Intelence, and it  
6 specifically states, save it for those patients that develop a  
7 certain type of mutation to those non-nukes, efavirenz and  
8 nevirapine.

9 And if you get this K103N mutation that will make those  
10 other drugs not good, Intelence will still be good, so you can  
11 then pull out Intelence from your back pocket and say, I have  
12 something to give you right now, when, if you had started them  
13 on Intelence, you might not have that anymore.

14 Q. Dr. Glatt, I just want to be clear: When it says  
15 "efavirenz," is that the chemical name? Is there a brand name  
16 for efavirenz?

17 A. Efavirenz and Sustiva are the same drug.

18 Q. Okay.

19 Then what is the commonly known name for the  
20 alternative? I'm not even going to try to pronounce it.

21 A. Nevirapine?

22 Q. Okay.

23 A. We don't use it that much anymore.

24 Q. Fair enough.

25 And then have you also looked at the IAS recommendation

1 during this time period to examine the claim that Intelence  
2 can be dosed or used in treatment-naive patients --

3 A. Yes.

4 Q. What are the guide -- what do the IAS recommendations say  
5 about that?

6 A. Exact same thing as the DHHS guidelines. It should not  
7 be used in treatment-naive patients.

8 Q. And then what about the recognized drug compendia --

9 A. Same exact --

10 Q. -- have they ever supported the use of Intelence in  
11 treatment-naive patients?

12 A. Same exact thing. They do not recommend them for  
13 treatment-naive patients. They're specifically indicated for  
14 those that have that K103N mutation that all the other NNRTIs  
15 would no longer be good for, but Intelence still will be good  
16 for.

17 Intelence is very good for that population, which is  
18 why you want to reserve it for that population and save it,  
19 and that's what the guidelines recommend.

20 Q. And, Dr. Glatt, you talked about that niche market.

21 Did you review documents in the course of this case  
22 that led you to believe that Janssen understood that its  
23 market for Intelence was very, very small?

24 A. Yes.

25 Q. Is this one of the documents that you reviewed in this

1 case?

2 A. Yes.

3 Q. Just explain to the jury what is your understanding of  
4 this Janssen internal document, what we see up here on the  
5 screen?

6 A. This document basically shows the potential patient  
7 population, patients with HIV and where they fit into the  
8 spectrum of potential uses for a drug like Intelence. They'll  
9 say I put Prezista as well, but let's focus on Intelence for  
10 now.

11 So the only indication based upon the label, based upon  
12 the studies, based upon the guidelines, based upon the  
13 compendia, would be in Category H, which, as you can see, is a  
14 very small percentage of the entire pie.

15 That would be 19,000 patients only. It would not be  
16 recommended, based upon the guidelines and certainly the  
17 label, in any of the other categories.

18 Q. Dr. Glatt, when you say -- I want to make sure I  
19 understand you. You're saying that only Category H is  
20 on-label for Intelence?

21 A. Correct.

22 Q. Okay.

23 And that represents that it is 19,000 patients.

24 Correct?

25 A. Correct.



1 Q. Okay.

2 If you look at the total patients here, do you know  
3 about what percent of the total HIV population that is?

4 A. About 2 percent.

5 Q. And just so the jury can visually see it, when we look at  
6 Categories E, F, G 1, G 2, and there is a graph there at the  
7 bottom, it says "Intelence BP share," and there's some  
8 percentages down there.

9 Do you see that?

10 A. Yes.

11 Q. Are all of those boxes, are they all off-label for that  
12 drug?

13 A. Anything but Box H is off-label.

14 Q. Okay.

15 Now, in your medical judgment, is there any of these  
16 boxes that you would, under certain circumstances, use  
17 Intelence off-label?

18 A. Yes.

19 Q. Explain that to the jury.

20 A. So as I mentioned, this critical mutation, this K103N  
21 mutation, essentially doesn't allow to use any of the other  
22 NNRTIs, any of the other non-nukes, other than Intelence.

23 So while that normally falls into Group H, it may  
24 actually fall into G 1.

25 Now, in those patients, the studies suggest don't use

1 an NNRTI. Use a PI. At this point in time, we, in general,  
2 would prefer a PI as the third arm of a regimen rather than an  
3 NNRTI because the studies show that the PIs are better.

4 So why is H the only indicating? Because that means  
5 they couldn't give a PI and you couldn't give them efavirenz,  
6 so therefore the only thing you're left with really is  
7 Intelence.

8 But I could understand, for whatever the reason, there  
9 might be a patient where they fall into the G 1 category where  
10 I would consider giving them Intelence, and I would prescribe  
11 it off-label in very selected patients in that category as  
12 well.

13 Q. So you, in your medical judgment, think there may be  
14 situations where you would go into just G 1 for a small number  
15 of patients?

16 A. Correct.

17 Q. And you can do that as a doctor, but is it your  
18 understanding that Janssen would be prohibited from marketing  
19 the drug to you in that fashion?

20 A. Yes, sir.

21 Q. Let's shift gears here. Let's talk about the potential  
22 safety concerns of pushing Intelence into treatment-naive  
23 patients.

24 Do you believe that that message is not only off-label  
25 but potentially dangerous to patients?

1 A. Yes.

2 Q. Explain why to the jury.

3 A. So it's off-label, that's -- that's quite clear. The  
4 label clearly states it only should be used in the patient H  
5 category that we just showed on the previous slide.

6 But for an individual patient or from the point of --  
7 perspective at large, I may be using up my ability to use  
8 Intelence when it's needed by using it too soon. That's why  
9 the guidelines suggest this sequencing idea.

10 It's not something I made up. It's not something a  
11 handful of people decided to do. It's what the experts across  
12 the country were doing, and, again, Dr. Rosenberg, he  
13 specifically states the exact same thing.

14 Q. So if I'm understanding correctly, if you have a  
15 treatment-naive patient and you give them Sustiva, you'll also  
16 have Intelence as a backup or most of the time have Intelence  
17 as a backup?

18 A. I would never use the word "always," but you certainly  
19 would hopefully have Intelence as a backup.

20 Q. But if you prescribe Intelence in the treatment-naive  
21 patient, you may lose the chance to prescribe Sustiva down the  
22 line?

23 A. Almost certainly, yes.

24 Q. Remind the jury: What happens when you run out of drugs  
25 as an HIV patient?

1 A. So when unfortunately we run out of drugs for an HIV  
2 patient, we unfortunately can't treat them. We try sometimes  
3 what we call salvage therapies where we're basically guessing  
4 as to what combination of available drugs left might be  
5 helpful.

6 We put them into studies and try them with drugs that  
7 haven't yet been approved, and we enroll them in studies. We  
8 have what we call compassionate release to use a drug that has  
9 not yet been FDA approved, but you can get it on what we --  
10 exactly what it sounds like, compassionate release because we  
11 have nothing else to offer this person.

12 And we now unfortunately, tragically -- historically  
13 then when we don't have anything to treat their underlying  
14 HIV, the vast majority of these patients will die.

15 Q. And, Doctor, kind of related to this, did Janssen at  
16 least begin studies in comparing Intelence to other protease  
17 inhibitors?

18 A. Yes. I wouldn't say other protease inhibitors because  
19 it's not a protease inhibitor, so to protease inhibitors,  
20 right.

21 Q. Okay.

22 What happened to that study, if you know?

23 A. Yes. The study was prematurely concluded because it  
24 showed that the protease inhibitor was better than the NNRTI,  
25 and that was one of the major foundation stones, if you wish,

1 for doctors usually preferring a protease inhibitor as the  
2 third arm of a drug regimen rather than an NNRTI.

3 Q. And is that further support for your opinion that  
4 Intelence should not be prescribed in treatment-naive patients  
5 under the prevailing standard of care during this time period?

6 A. Certainly, yes.

7 Q. In fact, did you review documents showing that the FDA  
8 had criticized Janssen for not disclosing the partial results  
9 of that study or the full picture in some of its marketing  
10 tease?

11 A. Yes. That's absolutely true.

12 Q. And I think we've discussed this already, but reasonable  
13 alternatives to Intelence, Sustiva and all of the other  
14 guideline-recommended drugs?

15 A. The different -- different category/class drugs, again,  
16 always with the baseline of two nukes, but a protease  
17 inhibitor or a different NNRTI, usually Sustiva, would be the  
18 preferred agents.

19 Q. And in your expert opinion, are those -- those preferred  
20 alternative drugs equally effective to Intelence?

21 A. Yes.

22 Q. Okay.

23 With respect to your ultimate conclusions, is it your  
24 expert opinion that marketing Intelence for treatment-naive  
25 patients was off-label during the relevant time period?

1 A. Absolutely.

2 Q. Is it your expert opinion that marketing Intelence to  
3 treatment-naive patients was proposing a clinically  
4 inappropriate use of the drug?

5 A. Absolutely.

6 Q. And is it your expert opinion that that marketing  
7 message, if implemented by a doctor, would cause them to  
8 violate the standard of care for HIV patients during that time  
9 period?

10 A. I think so, yes.

11 Q. Let's shift gears. Let's talk about the drug Prezista.  
12 What type of drug is Prezista, sir?

13 A. So Prezista belongs to the class of agent known as the  
14 PIs, the protease inhibitors, and that's a very powerful  
15 class.

16 During the relevant period of time, they were probably  
17 the preferred treatment drug, again always with the two nukes  
18 in the background, to treat patients initially.

19 Q. And when was Prezista approved initially by the FDA?

20 A. So Prezista received its initial approval in 2006, and  
21 then it had a change in the label in 2008 for an additional  
22 indication.

23 Q. Let's talk about the 2006 label first. What was Prezista  
24 indicated for?

25 A. So the initial label for Prezista, based upon the studies

1 that were solid, good Phase 3 studies, double-blind,  
2 prospective, randomized trials, demonstrated that Prezista did  
3 work, in fact, in treatment-experienced patients.

4 Specifically, the indication really was for people that had a  
5 prior protease inhibitor that had failed.

6 Q. And did the label of Prezista say that it had to be  
7 boosted with a different drug?

8 A. Yes.

9 Q. What did it have to be boosted with?

10 A. So there are -- at that point in time really one but then  
11 it became two drugs that would augment, if you wish, the  
12 pharmacokinetic, the dosing of the drugs, to soup up, make  
13 them better at what they did. And the main drug that we would  
14 boost, as we call it, the primary PI, was a drug called  
15 ritonavir.

16 Ritonavir originally came out as a PI itself, but it  
17 wasn't a very good one. But it was identified as being able  
18 to boost the efficacy, if you wish, of almost all the other  
19 PIs, and we would almost always, not necessarily for every PI,  
20 but always for Prezista, it always was given with ritonavir.

21 Q. And, Dr. Glatt, when the on-label studies are done for  
22 these drugs, do the individuals performing the studies, do  
23 they observe adverse reactions and other side effects of these  
24 drugs and make note of that?

25 A. Absolutely.

1 Q. And in certain circumstances, does that information then  
2 make it into the label because it's such a severe --

3 A. It always makes it into it, whether it's significant or  
4 only mildly significant. That's part of the label --

5 Q. Okay.

6 A. -- the adverse reactions that occur with a drug. They  
7 don't only put in serious ones; they put in everything.

8 Q. Fair enough.

9 Did Prezista's 2006 label have warnings, adverse drug  
10 reactions related to hypercholesterolemia and hyperlipidemia?

11 A. Yes, it did.

12 Q. Okay.

13 And just -- the jury has heard those words, but you're  
14 the expert. So what do those two things mean?

15 A. So the word "hyper" just means a lot of. "Hypo" means a  
16 little of. So hypertriglyceridemia, it just means, in the  
17 blood -- so that just means -- you put the word together -- a  
18 lot of triglyceride in the blood.

19 Hypercholesterolemia, same thing. Lots of cholesterol  
20 in the blood.

21 So it elevates the triglycerides and the cholesterol,  
22 especially the bad cholesterol in the blood. That's a side  
23 effect. That's an adverse reaction. That's something that we  
24 certainly wouldn't want, and that's something that you need to  
25 be aware of if a medication does that.



1 Q. And in 2008, in October 2008, did Prezista get an  
2 expanded label that allowed it to be marketed and it was  
3 deemed safe and effective for treatment-experienced patients?

4 A. Yes, it did.

5 Q. What was the basis of that label expansion? Did Janssen  
6 have to do something to get there?

7 A. Additional studies demonstrated that it could be  
8 effective in that group.

9 Q. Okay.

10 So for that portion, to get that expansion, they did it  
11 correctly, the way that it's supposed to work under the FDA  
12 process.

13 Fair enough?

14 A. Yes.

15 Q. Okay.

16 The underlying studies, did they -- what did they show  
17 about these issues of hypercholesterolemia and hyperlipidemia  
18 in the 2008 study -- the study that led to the 2008 label?

19 A. So they, again, demonstrated that it impacts in a  
20 negative way the lipid profile, specifically the triglycerides  
21 and the cholesterol.

22 Q. So this is a longer study.

23 Is that fair?

24 A. Yes.

25 Q. And it shows the same issues. And, in fact, the label

1 shows it got worse?

2 A. Well, there's more information in the label, and there  
3 definitely are going to be a significant percentage of  
4 patients that will have what are arbitrarily defined as class  
5 2, class 3 and class 4 severe adverse reactions. They are  
6 somewhat and arbitrary and they picked just a number and said,  
7 This many got this type of elevation, and then we picked  
8 another number that got that type of elevation, and another  
9 number that got that type of elevation. And it occurs in a  
10 significant number of patients taking the drug.

11 Q. And did that -- what the data showed, was it enough to  
12 move these issues from adverse reactions to serious adverse  
13 reactions in the 2008 label?

14 A. Yes. Well, there are different categories. Again, it's  
15 somewhat arbitrary, these categories, but they're very, very  
16 important. And the overall message is that it definitely  
17 impacts lipids in a significant percentage, not all, but in a  
18 significant percentage of patients.

19 I might add that Dr. Rosenberg, in his testimony, says  
20 the exact same thing: that everyone knows that Prezista  
21 impacts lipids.

22 Q. Okay. And we're going to get to the lipid issue. I want  
23 to just kind of set that up.

24 Let's examine the third of Janssen's marketing claims,  
25 that Prezista is safe and effective for treatment-naive

1 patients during that time period of 2006 to October 2008,  
2 before the label was changed.

3 Is there -- what does the 2006 label for Prezista show  
4 that it was indicated for?

5 A. So, again, the label has two specific qualifications in  
6 it. One is that they had to have been treated with an  
7 antiretroviral regimen beforehand. They weren't the naive  
8 group; they were previously treated.

9 And, again, that wasn't enough. They had to have  
10 demonstrated resistance to two or more other protease  
11 inhibitors, and then it would be appropriate. And, in fact,  
12 the IAS guidelines, in 2010, said, We preferred not to use  
13 Prezista so early because of the fact that, again, Prezista is  
14 good when you have other PI resistance. It still may be  
15 effective.

16 So that's why this label was the way it was, that you  
17 wanted it used only initially in patients that had prior PI  
18 resistance.

19 Q. And you said two protease inhibitors or --

20 A. Well, more than one.

21 Q. More than one. More than one means two.

22 Right?

23 A. Two or more, right.

24 Q. Two, three, four, five, that's where the drug came -- was  
25 appropriate --

1 A. Right.

2 Q. -- under this -- this way.

3 A. It's a later one, so all the earlier classes, if they had  
4 developed resistance to the earlier classes, Prezista did  
5 often still work. So you'd want to, again, reserve it to a  
6 certain extent.

7 Q. And in that 2006 label, did it specifically state that  
8 the studies had not yet been done that would justify using  
9 this drug in treatment-naive patients?

10 A. Correct.

11 Q. Let's look at the guidelines from 2006 to 2008.

12 What did the DHHS guidelines say about using Prezista  
13 in treatment-naive patients during that time period?

14 A. That there was insufficient data to recommend its usage  
15 for initial therapy in treatment-naive patients.

16 Q. Okay.

17 And were the guidelines updated multiple times during  
18 that time period?

19 A. Yes, they were.

20 Q. Okay.

21 And did that recommendation stay consistent, that we  
22 don't have sufficient information yet?

23 A. Until October of 2008 it did.

24 Q. Okay.

25 And you mentioned the IAS recommendations. What did

1 the IAS recommendations say about using Prezista in  
2 treatment-naive patients?

3 A. So it initially said the same thing. It's not  
4 recommended in treatment-naive patients. But even after  
5 Prezista received its indication for treatment-naive patients,  
6 the IAS guidelines stated it's considered by many as less  
7 attractive in initial therapy because it's so good in the  
8 sense that you might want to reserve it for those PI-resistant  
9 cases.

10 Q. And --

11 A. Here's an example of where the recommendations might  
12 slightly differ from the label.

13 Q. Okay.

14 And in this particular case, the recommendations and  
15 the guidelines are actually more restrictive.

16 Is that fair?

17 A. Yes. That's exactly what I'm pointing out. That the  
18 usage of these agents, the label says you could use it then.  
19 And I'm not saying you can't have used it then, but there is a  
20 caveat, a thought in the back of your mind that if you could  
21 use still an earlier PI and possibly save Prezista, that  
22 wouldn't be inappropriate.

23 I'm not going to say that somebody who gave Prezista  
24 earlier is wrong. The guidelines allowed that, and the label  
25 allows that. It's just something to be aware of.

1 Q. Let me ask it this way. I understand that -- or you  
2 understand we're talking at least for this claim about the  
3 period between 2006 and 2000- --

4 A. During that period of time, absolutely not.

5 Q. Does what the International AIDS Society said about  
6 Prezista in naive patients in 2010, does that support your  
7 opinion that at least between 2006 and 2008, doctors should  
8 not, under the standard of care, have been pushing Prezista to  
9 naive patients?

10 A. Yes. Under normal circumstances, correct.

11 Q. And does that -- the IAS recommendation in 2010, does  
12 that show a certain level of -- a lack of consensus, even over  
13 kind of what the label had?

14 A. You know, not everything in medicine is as clear-cut as  
15 we'd like it to be. There are situations where experts will  
16 disagree.

17 Q. And let's look at the drug compendia. Between 2006 and  
18 2008, did any of the recognized compendia support the use of  
19 Prezista in treatment-naive patients?

20 A. They did not.

21 Q. Now, Doctor, given the fact that the label eventually did  
22 change, how does that come into your opinion? If Janssen  
23 ended up being right, they predicted, I guess, that, you know,  
24 it would change and they marketed it that way, why is that  
25 still problematic?

1 A. You have to practice medicine in the year that you're in.  
2 If we're practicing back in the relevant period of time with  
3 today's practice, we wouldn't be using any of these agents.  
4 You practice in the year that you're in. You practice in the  
5 time that you're in.

6 And based upon the guidelines and the studies, it  
7 wasn't yet indicated in that group of patients. There is the  
8 potential for harm. There is the potential for side effects.  
9 And, again, if you take the IAS statement from 2010, that's  
10 certainly not appropriate in 2006 to 2008.

11 Reasonable people can disagree on that, but the  
12 guidelines, which is how the label -- which is how the  
13 pharmaceutical industry is allowed to market it, clearly did  
14 not allow marketing it in that indication between 2006 and  
15 October 2008.

16 Q. And then during the relevant time period, 2006 to October  
17 2008, were there reasonable alternatives for a doctor that  
18 wanted to prescribe a drug in treatment-naive patients, or  
19 particularly a protease inhibitor?

20 A. Yes, there were.

21 Q. What were those alternatives?

22 A. So there were two major ones that people would be using  
23 in those days. I'll refer to them by brand names, Kaletra and  
24 Reyataz.

25 MR. WIRMANI: Judge, this is a good stopping point.

1 I don't know if we're going --

2 THE COURT: Not today, but we are going to start  
3 going to 5 starting tomorrow. So absent a few days.

4 So why don't we do this. I'm going to adjourn the  
5 jurors for today. Folks, I'm going to be talking to the  
6 lawyers about making adjustments to the trial schedule. For  
7 now, though, tomorrow, at least, I can tell you is 9:15 to 5.  
8 So if you guys are ready by 9:15, we will start at 9:15 and  
9 actually begin our housekeeping earlier than 9 so we're not  
10 holding you up.

11 But there are going to be some half days or 12 p.m.  
12 forward Fridays and things of that nature that we're going to  
13 adjust, and I will let you know the full schedule tomorrow  
14 morning if that works.

15 So for now, let's dismiss the jurors for the day. I'll  
16 see you all back at 9:15 ready to go.

17 And, Counsel, remain.

18 (Court adjourned at 4:00 p.m.)  
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FEDERAL OFFICIAL COURT REPORTER'S CERTIFICATE.

- - - - -

I certify that the foregoing is a correct transcript from  
the record of proceedings in the above-entitled matter.

I

/S/ Megan McKay-Soule, RDR, CRR      May 20, 2024

Court Reporter

Date

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